EXHIBIT A

Notice

PART 1

UNITED STATES BANKRUPTCY COURT FOR THE DISTRICT OF MASSACHUSETTS EASTERN DIVISION

In re:

NEW ENGLAND COMPOUNDING PHARMACY, INC.,

Chapter 11

Case No. 12-19882-HJB

Debtor.

NOTICE OF PLAN PROPONENTS' LIST OF EXHIBITS AND DECLARATIONS TO BE OFFERED IN LIEU OF DIRECT TESTIMONY IN CONNECTION WITH THE HEARING SCHEDULED FOR TUESDAY, MAY 19, 2015 ON CONFIRMATION OF THE SECOND AMENDED JOINT CHAPTER 11 PLAN OF NEW ENGLAND COMPOUNDING PHARMACY, INC.

In connection with the hearing (the "Confirmation Hearing") scheduled for May 19, 2015 at 10:00 a.m. on confirmation of the Second Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. [Dkt. 1308], Paul D. Moore, the Chapter 11 Trustee (the "Trustee") for the chapter 11 estate of New England Compounding Pharmacy, Inc. ("NECC" or the "Debtor"), and the Official Committee of Unsecured Creditors of NECC (the "Official Committee," and together with the Trustee, the "Plan Proponents"), intend to offer into evidence the declarations (the "Declarations") identified as exhibits on Exhibit "A" hereto.

Consistent with this Court's Order granting *Plan Proponents' Request to (I) Submit Declarations as Direct Testimony of Declarants and (II) Excuse Declarants from Attendance at Hearing to Consider Confirmation of the First Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc.* [Dkt. No. 1317] (the "Hearing Order"), the Plan Proponents will request that the Declarations be entered into evidence in lieu of direct testimony. The Plan Proponents do not intend to call any of the declarants as witnesses at the Confirmation Hearing.

The Plan Proponents reserve all rights to offer into evidence any additional declarations that are filed with this Court prior to the deadline of May 15, 2015 at 5:00 p.m. set forth in the Hearing Order.

Dated: May 14, 2015

Boston, Massachusetts

Respectfully submitted,

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Counsel to the Official Committee of Unsecured Creditors of New England Compounding Pharmacy, Inc.

EXHIBIT A PLAN PROPONENTS' EXHIBITS

PLAN PROPONENTS' EXHIBIT NO.	DESCRIPTION
1	Declaration of Michael F. Barrett, Esq. in Support of Confirmation of First Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. and for Approval of Inspira Settlement [Dkt. No. 1225]
2	Declaration of Kimberly A. Dougherty in Support of Confirmation of First Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. and for Approval of the High Point Settlement [Dkt. No. 1226]
3	Declaration of Kimberly A. Dougherty in Support of Confirmation of First Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. and for Approval of the Victory Settlement [Dkt. No. 1227]
4	Declaration of Frederic L. Ellis in Support of Confirmation of First Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. and for Approval of ARL Settlement [Dkt. No. 1228]
5	Declaration of Patrick T. Fennell in Support of Confirmation of First Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. and for Approval of Insight Settlement [Dkt. No. 1229]
6	Declaration of J. Scott Sexton in Support of Confirmation of First Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. (Relating to Settlement with Insight Health Corp., and Others - Virginia) [Dkt. No. 1230]
7	Declaration of Thomas M. Sobol in Support of Approval of the Unifirst Settlement and in Support of Approval of the First Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. [Dkt. No. 1231]
8	Declaration of Matthew K. Doonan, Esq. in Support of Confirmation of First Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. [Dkt. No. 1232]

PLAN PROPONENTS' EXHIBIT NO.	DESCRIPTION
9	Declaration of Henri G. Minette in Support of Confirmation of First Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. [Dkt. No. 1233]
10	Declaration of Gregory Earl Thomas in Support of Confirmation of First Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. [Dkt. No. 1234]
11	Declaration of Mark G. Ledwin on Behalf of Preferred Mutual Insurance Company in Support of Confirmation of First Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. [Dkt. No. 1235]
12	Declaration of Frederic L. Ellis Concerning the National Compensation Program Established by the Proposed Amended Plan of Reorganization [Dkt. No. 1236]
13	Plaintiffs' Steering Committee's Declaration in Support of Approval of the First Amended Joint Chapter 11 Plan [Dkt. No. 1237]
14	Joint Declaration of Anne Andrews and Michael Coren, as Representatives of the Co- Chairs of the Official Committee of Unsecured Creditors, in Connection With The Official Committee's Support for Confirmation of the First Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. and Approval of the Settlements Contained Therein [Dkt. No. 1238]
15	Declaration of David J. Molton in Support of the Joint Motion of the Chapter 11 Trustee and the Official Committee of Unsecured Creditors for an Order Approving Plan Support and Settlement Agreement with Liberty Industries, Inc. [Dkt. No. 1260]
16	Declaration of Rita A. Bunch in Support of Confirmation of First Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. [Dkt. No. 1261]
17	Declaration of Joseph A. Ziemianski In Support of Confirmation of First Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. [Dkt. No. 1284]

PLAN PROPONENTS' EXHIBIT NO.	DESCRIPTION
18	Declaration of Liberty Industries, Inc. in Support of Confirmation of First Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. [Dkt. No. 1293]
19	Declaration of Jung W. Song on Behalf of Donlin, Recano & Company, Inc. Regarding Voting and Tabulation of Ballots Accepting and Rejecting the First Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. [Dkt. No. 1294]
20	Declaration of Amanda J. Cox, Esq. in Support of Confirmation of First Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. [Dkt. No. 1296]
21	Declaration of Michael T. Ryan, Esq. on Behalf of Pharmacists Mutual Insurance Company in Support of First Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. [Dkt. No. 1301]
22	Declaration of Brian Robischeau in Support of Confirmation of First Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. [Dkt. No. 1306]
23	Declaration of Stephen B. Darr In Support Of Confirmation of the Second Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. [Dkt. No. 1309]
24	Declaration of Chapter 11 Trustee in Support of Confirmation of Second Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. [Dkt. No. 1319]
25	Supplemental Declaration of Thomas M. Sobol Concerning the National Compensation Program Established by the Proposed Amended Plan of Reorganization [Dkt. No. 1322]
26	Supplemental Declaration of Fredric L. Ellis Concerning the National Compensation Program Established by the Proposed Amended Plan of Reorganization [Dkt. No. 1323]
27	Declaration of Harry M. Roth Concerning the National Compensation Program Established by the Proposed Amended Plan of Reorganization [Dkt. No. 1327]

Certificate of Service

I, Michael R. Lastowski, hereby certify that on May 14, 2015, I caused a copy of the foregoing *Notice of Plan Proponents' Exhibit List in Connection with the Hearing Scheduled for Tuesday, May 19, 2015 on Confirmation of the Second Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc.*, which was filed using this Court's ECF system, to be served electronically upon those parties registered to receive ECF service.

/s/ Michael R. Lastowski
Michael R. Lastowski

PLAN PROPONENTS' EXHIBIT 1

UNITED STATES BANKRUPTCY COURT DISTRICT OF MASSACHUSETTS EASTERN DIVISION

In re:

NEW ENGLAND COMPOUNDING PHARMACY, INC., Debtor.

Chapter 11 Case No. 12-19882-HJB

DECLARATION OF MICHAEL F. BARRETT, ESQ. IN SUPPORT OF CONFIRMATION OF FIRST AMENDED JOINT CHAPTER 11 PLAN OF NEW ENGLAND COMPOUNDING PHARMACY, INC. AND FOR APPROVAL OF INSPIRA SETTLEMENT

Michael F. Barrett, Esquire, being of lawful age does set down and state the following:

- of the New England Compounding Pharmacy, Inc. ("NECC") [Docket No. 1054] (as amended at Docket No. 1154 and thereafter, from time to time, and including all exhibits and supplements thereto, the "Plan") and, more specifically, in support of approval of the Inspira Health Network, Inc. ("Inspira") Settlement and Non-Debtor Third Party Release which is a part of the proposed Plan. I am competent to testify under oath to the matters set forth herein if called to do so in that I chaired the committee comprised of New Jersey claimant lawyers, members of the Official Creditors' Committee ("OCC"), members of the Plaintiffs Steering Committee ("PSC") of the NECC Products Liability Multi-District Litigation ("MDL"), the NECC Trustee, Paul Moore, and his representatives, that negotiated the proposed \$16 Million settlement with the Inspira. I therefore have personal knowledge regarding the Settlement and the related negotiations, matters at issue, and competing positions of the parties. I also have personal knowledge as to all other matters set forth in this Declaration.
- 2. I am an attorney at law duly admitted to the Bar of the State of New Jersey, State of New York, and Commonwealth of Pennsylvania and District of Columbia. I am a shareholder

of the Southeastern Pennsylvania and Southern New Jersey regional law firm of Saltz,

Mongeluzzi, Barrett & Bendesky, PC. My personal law practice focuses on the litigation and

trial of medical malpractice, professional negligence, pharmaceutical drugs and medical devices

products liability, civil rights and a broad spectrum of other civil litigation cases. I am a

Certified Civil Trial Attorney by the Supreme Court of New Jersey. I am also a Fellow of the

American College of Trial Lawyers, a Certified Civil Pre-Trial and Trial Advocate of the

National Board of Trial Advocates, and a Fellow of the Advisory Board of Litigation Counsel of

American.

3. I am admitted *pro hac vice* in the *NECC* MDL in connection with my firm's representation of thirty-six individual New Jersey claimants who received one or more injections of NECC's allegedly contaminated methylprednisolone acetate ("MPA") at one of the following Southern New Jersey healthcare facilities: (a) Inspira's Vineland and Elmira healthcare facilities (which facilities were formerly known respectively as South Jersey Regional Medical Center and South Jersey Hospital- Elmira¹); and/or (b) Premier Orthopaedic Surgical Center, Inc.'s ambulatory surgical center facility in Vineland, New Jersey.² My clients include individuals who developed fungal meningitis and other spinal fungal infections. Some have had very long term hospitalizations and complications as a result of the contaminated MPA injections.

¹ At the time the contaminated MPA was administered in 2012, Inspira Health Network, Inc. was known as "South Jersey Health System, Inc.", and its medical facilities in Vineland and Elmer, New Jersey, were owned and operated by a subsidiary named "South Jersey Hospital, Inc." In 2013, South Jersey Health System became a part of the "Inspira Health Network" in connection with a consolidation of southern New Jersey community hospitals.

² Premier Orthopaedic Surgical Center is owned by many of the doctors associated with Premier Orthopaedics and Sports Medicine Associates of Southern New Jersey, LLC. ("Premier Ortho"), which is also named in many suits in the MDL due to the role of Premier Ortho's Dr. Kimberly Smith-Martin in prescribing and administering NECC's MPA to patients at Inspira's two facilities. For ease of reference, "**Premier**" used further in this Declaration shall mean and refer to both Premier Orthopaedic Surgical Center and Premier Ortho.

- 4. I have been appointed by the NECC PSC to serve as co-chair of the PSC's New Jersey State Claimants Subcommittee designated to prosecute the state specific claims of NECC's victims injured in New Jersey ("NJ-PSC Subcommittee").³ In that capacity, I was entrusted and tasked to coordinate and manage the investigation and prosecution of the New Jersey claimants' cases in the MDL against New Jersey clinical entities and various individual New Jersey health care providers who were involved in the selection, prescription and/or administration of NECC's preservative free MPA that was the subject of the NECC MDL. New Jersey was one of the states hit hardest by NECC's recalled preservative free MPA. Claimants suing from New Jersey comprise one of the largest plaintiff groups in the NECC MDL.
- 5. I and other members of the NJ-PSC Subcommittee have been and are cooperatively investigating the liability of Inspira and Premier relating to the contaminated MPA injections. Among other things, we have obtained and reviewed records relating to NECC and NECC's interactions and dealings with Inspira and Premier from the following sources: government agencies and Congressional investigative committees; documents that Inspira and Premier produced to the PSC pursuant to subpoenas; and documents that NECC's Trustee made available to the OCC, PSC and the NJ PSC subcommittee for specific use in connection with the Inspira mediation before Professor Eric Green, Esq. Members of the NJ-PSC Subcommittee and I have also consulted with various experts in the fields of drug compounding, anesthesia, pain management, infectious diseases, ambulatory surgical facility management, and clinical formulary management. Based upon these investigative efforts, I believe that I and members of

³ Members of the NJ PSC Subcommittee include attorneys from the law firms of Andrews & Thornton (which firm serves also as an OCC co-chair member representative), Cohen Placitella & Roth (which firm serves also as an OCC co-chair member representative), Golomb & Honik, PC, Hoffman DiMuzio, Law Offices of Jeffrey M. Keiser, The Orlando Firm (also a member of the PSC) and Soloff & Zervanos, PC.

the NJ-PSC Subcommittee developed sufficient information, knowledge and resources to prosecute the cases against Inspira and Premier on behalf of NECC MPA tort victims. We have obtained and/or are able to obtain required Affidavits of Merit as to New Jersey health care providers and facilities targeted by MDL plaintiffs. The information the NJ PSC Subcommittee has developed enables me to identify, understand and weigh the various liability and damages factors involved in the NECC litigation to both meaningfully participate in mediation with Inspira Health Network's representatives on behalf of injured plaintiffs and to make the statements and offer the professional opinions contained in this declaration.

- 6. During the second half of 2013, Inspira Heath Network agreed to participate in a mediation program offered by the OCC, the PSC and the Trustee. While Inspira chose not to enter into the mediation program established by the MDL Court, it nonetheless agreed to mediate privately with the OCC, PSC and Trustee before Professor Eric Green, who was designated by Judge Zobel as the lead mediator in the MDL's Court's mediation program. Judge Zobel was apprised of the Inspira private mediation and was periodically provided status reports on its progress.
- 7. The following claimants' negotiating committee represented the interests of the injured New Jersey NECC claimants in the mediation with Inspira: (a) the NECC Trustee, Paul D. Moore, Esq. (in addition to himself, Mr. Moore was also represented by his attorneys Michael R. Gottfried and Jeffrey D. Sternklar); (b) member representatives of the OCC (Anne Andrews, Esq., Michael Coren, Esq., Harry Roth, Esq. and John Thornton, Esq.; (c) counsel for the OCC (David Molton, Esq.); (d) members of the PSC (Patrick T. Fennell. Esq., Thomas Sobol, Esq., the PSC's Lead Counsel, and Mark Zamora, Esq.); and (d) members of the NJ-PSC

Subcommittee (including myself, Jeffrey P. Fritz, Esq., Ernest L. Alvino, Esq., Mary T. Gidaro, Esq., Jeffrey M. Keiser, Esq., and Steven Resnick, Esq.).

- 8. Under the auspices of the mediator, Professor Green, Inspira and the claimant's negotiation committee held numerous conference calls starting in the fall of 2013 and continuing until June, 2014. During those calls, the parties exchanged demographic information on the claims, including nature and incidence rates of various categories of claims corresponding closely to the Center for Disease Control ("CDC") categories, but modified to reflect the unique experience among the New Jersey exposed population. The good faith exchange of information permitted the mediation parties to agree upon the number of patients who were treated at Inspira's two facilities, that is, 213 individual patients, as well as the distribution of disease and injury among the group of Inspira patients. Inspira also provided pertinent financial and insurance information. As part of this pre-mediation session process, the parties submitted to the mediator and exchanged among themselves confidential mediation memoranda outlining each side's positions on legal claims, injuries and defenses. Accordingly, each side was able to proceed into mediation fully aware of each side's position and the basis for that position and to assess the strengths and weakness of their respective positions.
- 9. On July 2, 2014 and July 24, 2014, lengthy mediation sessions were held in New York City.

⁴ As part of its epidemiological investigation into the cause and extent of the 2012 fungal infection outbreak, the CDC established a set of case definitions to determine disease incidence rates associated with NECC's contaminated drugs: (1) meningitis; (2) meningitis and paraspinal/spinal infection; (3) stroke without lumbar puncture; (4) paraspinal/spinal infection; (5) peripheral joint infection; (6) paraspinal/spinal infection and peripheral joint infection; and (7) death. Since unlike other states no acute deaths in New Jersey related to the outbreak had occurred and been reported to the CDC or Inspira, for global negotiation purposes an alternative seventh category was created: "No CDC Category". This category captured "contaminated MPA exposed only" cases as well cases where the claimant underwent diagnostic testing such as lumbar puncture and/or an MRI but had no positive findings for infection.

- 10. During the first session on July 2, counsel representing plaintiffs made presentations concerning some of their clients to illustrate the claims and the breadth of injuries involved. Following that, under the mediator's auspices the parties discussed at length the strengths and weaknesses of the liability case against Inspira, which liability Inspira steadfastly denied existed. The strengths and weaknesses of the liability cases against various other actors involved in the NECC cases, many of whom were co-defendants named by the plaintiffs, were also discussed. It was made known to the claimants' negotiation team that Inspira had issues with its insurance carriers over coverage that bore upon the negotiations.
- 11. The settlement negotiations were at times contentious. They were throughout very hard fought and conducted on an arm's-length basis. Professor Green at all times was actively involved in the process, ably forcing the various factions to dispassionately, logically and realistically reexamine their positions, authorities and facts, and to consider things that one side or the others previously had not considered. His efforts brought about movements and realistic bargaining on each side.
- 12. The mediation session concluded during the evening of July 24, 2014, with the parties reaching an agreement on the essential financial terms pursuant to which Inspira and its insurers would contribute \$16 million to the settlement fund. Following that, counsel for the OCC, PSC and Trustee negotiated the terms of the written settlement agreement that is now before the Court. I and OCC's co-chair Michael Coren, also a member of the New Jersey Bar, negotiated the terms of the Agreement's joint tortfeasor release provisions, to assure that claims against other potentially responsible parties, including Premier, were preserved.
- 13. Following the mediation and while the Plan documents were being prepared and finalized, members of the OCC, MDL PSC and NJ-PSC subcommittee met and conferred on

numerous occasions to develop and agree upon a claims resolution facility and distribution matrix for the portion of the Inspira settlement specifically earmarked and allocated under the proposed plan of reorganization (the "Plan") to claimants administered contaminated NECC drugs at Inspira. We modeled the claims resolution facility upon the proposed Chapter Plan's Tort Trust's claims resolution facility. We all agreed that the Plan's Tort Trust distribution matrix should serve as the basis for distribution with modifications (via a supplementary matrix) designed to provide compensation reflecting the range and extent of injuries of the Inspira claimants sharing this allocated fund. The process of reaching agreement was consensus-driven and reflects the input and efforts of numerous NJ-PSC subcommittee members, members of the PSC and members of the OCC.

THE REASONABLENESS OF THE INSPIRA SETTLEMENT

14. If allowed by this Court, the Plan will provide the NECC estate with an amount projected to exceed \$200 million. In this regard, the Plan contemplates court approval of numerous settlements of various claims and disputes between and among the NECC estate, certain of NECC's contractors and their insurance companies, NECC's product testing laboratory, various clinics and hospitals that administered contaminated MPA and personal injury claimants, one of which is the \$16 million proposed settlement with Inspira and its insurers. The \$16 million Inspira Settlement provides that fifteen percent (15%) of it will be distributed as part of the general NECC bankruptcy estate pursuant to a Chapter 11 Plan with the remaining eighty-five percent (85%) allocated to go into a separate Inspira Claims Facility established under the Plan to make compensation payments exclusively to NECC personal injury claimants who were administered contaminated NECC drugs at an Inspira facility in New Jersey. As mentioned, there were according to Inspira's records 213 individuals administered NECC

preservative free MPA drawn from vials in the three recalled lots. The allocation between the general plan distribution and the segregated fund for Inspira patients reflects recognition of the number of persons with unique claims against Inspira as well as the fact a global settlement must deal with the existence of NECC's and other's contribution claims against Inspira and contribute towards bankruptcy administration expenses

- 15. I believe that the Inspira settlement is fair, reasonable and adequate, and can and should be approved as part of the Chapter 11 approval proceedings for at least the following reasons:
- a. Result: The \$16 million settlement achieves fair, reasonable and adequate value from Inspira for both the NECC creditors in general and especially those creditors who were injured as result of being administered contaminated MPA at Inspira's two New Jersey facilities. In assessing and weighing the value of the claims against Inspira being compromised against the value to the estate and its creditors, I believe the result of the settlement provides a greater recovery to NECC's bankruptcy estate and its creditors than is possible through litigation, and without the corresponding delay, expense and risks associated with any such litigation.
- b. In stating this professional opinion, I have taken into account, on the one hand, the array of injuries suffered by the 213 exposed Inspira patients. Based upon examination and review of numerous Inspira claimants' medical records or reports on their condition the NJ-PSC Subcommittee had available to them, I can inform the Court the claims against Inspira fell into discrete ascertainable categories well matching the CDC's fungal infection outbreak case definition categories, with the exception there were no cases of acute death as occurred in several other states. That said, there was a substantial variance in degree of harm and duration of injury

⁵ See footnote 4 *supra*.

among the members of the cohort. For example, some of the injury claims were very modest, being no more than having been injected with the contaminated medication and consequentially suffering reasonable and understandable upset and concern lasting many, many months because of the novelty of the outbreak situation, reports of delayed effect onset and the inability of the medical community to definitely state that there was no further risk or concern. A significant number of the Inspira exposed population, however, were much more seriously injured. Many were required to undergo one or more painful lumbar puncture diagnostic/monitoring procedures as well as repeated MRI's and blood tests. Many were diagnosed with fungal infections (meningitis and/or spinal or para-spinal abscesses) which required medical treatment for many months at least; some of these patients are still being treated today, more than two and a half years later. Some of the Inspira patients required surgery to debride abscesses that formed in tissue at or near injection sites. And a good number of the exposed patients were put on long courses of potent antifungal medications. The anti-fungal medications prescribed had terrible side effects and risks and often required hospital stays in order to initiate the treatment. Known side effects associated with these medications (such as disturbing hallucinations, liver or kidney function impairment, rashes and skin eruptions, very painful light insensitivity and long-lasting cognitive impairment) were often reported. In addition there were a number of exceptional injuries among the infected patients, such as a heart attacks and serious neurological disorders. These categories, incidence numbers and variation in degree and duration of harm of the cohort were all taken into account when negotiating the settlement with Inspira and its insurance carriers and agreeing in principle to the \$16 million global number. These were also considered and taken into account in devising the Inspira claims resolution distribution matrix for the Inspira cohort's earmarked fund.

- c. While steadfastly maintaining that it was not legally liable and had numerous valid defenses (which I address below), Inspira and its insurers nonetheless agreed that, in exchange for a non-debtor release and injunction providing them protection against any and all of the numerous competing claims and substantial potential liability relating to NECC's compounded drugs, they are willing to make a very substantial contribution of \$16 million to the NECC estate, . This amount should provide considerable payments to qualified individual Inspira claimants who qualify and make application to the Inspira Claims Resolution Facility for compensation. It also provides a substantial amount of funds for general Plan purposes, particularly other tort claimants not treated in New Jersey by Inspira.
- d. <u>Collectability</u>: The Inspira settlement of \$16 million is a substantial portion of Inspira's entire available insurance coverage. I believe that the settlement amount of \$16 million is an amount that is more than could be secured were the NECC estate and personal injury claimants to succeed in litigation, especially when taking into account the costs and expenses of any such litigation and inevitable appeals. The settlement ensures prompt recovery without the risk of depleting, through years of litigation, judgments among competing claimants that otherwise might exhaust amounts available for competing claimants.
- e. <u>Disputed Liability</u>: The prospects for recovery against Inspira in litigation were and are far from certain. While I and members of the NJ-PSC Subcommittee believe that Inspira's negligence could be proven, the issues of causation and allocation of fault are more difficult issues. An inability to prove proximate causation between Inspira's culpable conduct and the plaintiffs' injuries could raise serious issues that defeat liability entirely. Inspira maintained that it acted reasonably and within applicable standards of care, did not know of

NECC's shortcomings and indeed viewed itself a victim of NECC and the NECC insider's criminal conduct. And, even if successful in proving Inspira's causative contribution to its patients' injuries, there was a more pivotal issue of its comparative fault under New Jersey's comparative fault scheme. More particularly, NECC claimants would need to establish that Inspira was at least sixty percent (60%) at fault in order to have Inspira held jointly and severally liable for any claimant's entire judgment. ⁶ Thus, the reality of this case is that Inspira's relative fault – while a jury question we believe claimants would likely prevail on – had to be seriously considered and factored into valuing the claims and the likely recovery. Accordingly, in negotiating the Inspira settlement, all parties took into account and considered the nature and degree of other NECC potentially responsible actors' relative fault, including NECC, NECC's employees and officers, Premier's doctors, ARL, Liberty, Victory and Unifirst. Taking these liability factors into account, it is my professional opinion that the Inspira settlement is equitable, fair, reasonable and adequate.

f. Plan Progress/Interests of Creditors: The approval of the Inspira Settlement is essential to the approval of a Chapter 11 plan and, I believe, is clearly in the best interest of the estate's creditors. The victims of the outbreak have already waited for over two and one-half years for compensation, and confirmation of the Plan will allow distributions from the Tort Trust to begin to be made to them. Both the Inspira Settlement and the Chapter 11 eliminate the danger of races to the courthouse and to trial that exist here given the limited amounts of insurance

⁶ Under New Jersey law, if a party is found to be less than 60% responsible for total damages, it can be held responsible only for payment of that percentage of damages directly attributable to its negligence. N.J.S.A. 2A:15-5.3. Of course there is was also the risk —one we believed remote—that a jury would ascribe no liability against Inspira. Still the risk existed.

coverage and number of potential claims. For the reasons I set forth in this Declaration, I have strongly recommended to each of my firm's clients that they vote in favor of the Plan.

Complexity, Expense, Inconvenience and Delay in Pursuing Litigation. The g. litigation that would be required to be pursued if the Inspira settlement is not approved would be complex, expensive and protracted. Indeed, we know this first hand as I and members of the NJ-PSC Subcommittee litigate in parallel proceedings against Premier defendants, who refuse to even discuss settlement even two and a half years after the event. Under the current MDL case management orders New Jersey claimants trials against Premier will not begin until sometime around early summer of 2016. Before then we anticipate numerous depositions being taken and following that dispositive motions and extensive in limine motion battles. Moreover, any litigation against Inspira likely would be protracted and further delayed by inevitable appeals, such that any recovery for the benefit of tort claimants would be significantly delayed. Absent settlement, Inspira would vigorously contest its liability, all the while reducing the amount of available insurance coverage—its remaining insurance coverage being of the type that defense costs reduce the amount of indemnity coverage available. Therefore, I do not believe that it is in the best interest of the NECC estate or the personal injury claimants to pursue the complex, lengthy, and costly litigation that would be required if the Inspira settlement is not approved. Many of the personal injury claimants are suffering substantial financial hardship as a result of the injuries caused by the contaminated MPA, and they have a compelling need to secure a recovery as soon as possible. The proposed settlement will greatly enhance the likelihood of achieving that goal.

The Non-Debtor/Third Party Releases are Necessary to Bring About the Inspira Settlement

16. The contemplated Inspira settlement is conditioned upon confirmation of a Plan that provides non-debtor or third party releases, both to contributors as well as certain parties

who are not direct contributors. The scope of these releases is limited to claims arising from contaminated NECC products. These releases will have to be approved by this Court at confirmation (the settlement agreements, by their terms, only become wholly effective upon confirmation of a plan containing such releases). These non-party third party releases are a critical component of the Inspira settlement, particularly with respect to persons and entities who are not directly contributing funds as part of this settlement such as Inspira's directors, officers, employees and insurers. Inspira as a New Jersey non-profit charitable entity has limited liability under New Jersey law, but still remains liable over and above this charitable immunity limit for the negligence of its employees, officers and servants. New Jersey Claimants were all prepared to name as co-defendants Inspira's directors, officers, employees and agents once identified during discovery as having potential responsibility for the contaminated NECC drugs. Understandably Inspira insisted it would not settle without obtaining full releases of such employees' and agents' liability, as well as the release of any claims against Inspira's insurers arising out of the NECC contaminated drugs.

- them, Inspira and its insurers would not have agreed to pay \$16 million to settle the NECC claims. The amount we obtained reflects Inspira's desire to completely and once and for all put the administration of contaminated NECC drugs to patients at Inspira's facilities behind it and move on. As a direct participant in the settlement negotiations, I understood that it was a *sine qua non* of reaching a settlement that the Plan provide for a channeling injunction and third party releases to enable Inspira to once and for all time put this episode behind it.
- 18. The benefits to the NECC estate from the \$16 million Inspira settlement, the majority of which will flow to the tort claimants and particularly the patients exposed at Inspira's

two New Jersey facilities, is a principal reason why the third party releases are reasonable. Since it is anticipated that personal injury claimants will hold the vast majority of allowed claims, the vast majority of the net proceeds of the Inspira settlement (after payment of allowed administrative expenses and priority claims, if any) will be distributed to personal injury claimants. Moreover, the settlement funds will be distributed in a fair and equitable manner, rather than as a result of a race to the courthouse.

The Inspira Claims Facility is a Fair and Equitable Means to Distribute the Inspira Settlement.

19. As stated above, following the negotiation of the \$16 million settlement amount, members of the OCC, PSC and NJ-PSC Subcommittee prepared a proposed Inspira Claims Resolution Facility and Supplementary Matrix to handle the distribution of the \$16 million settlement allocated for distribution to Inspira patients only. The matrix and claims procedures are patterned on the National matrix with changes to reflect the Inspira cohort's experience and needs. As part of the process, several proposed claims administrators submitted proposals and were interviewed. On the basis of those interviews and proposals, Edgar C. Gentle, III, Esquire was selected to serve as the Inspira Claims Facility administrator. All of the decisions relating to the claims facility, the claims processes, the supplemental matrix and the claim administrator were made by consensus of the counsel representing Inspira claimants who desired to participate in developing this claim allocation and distribution infrastructure. I believe they are all fair, reasonable, adequate and equitable measures and decisions and should be approved by this Court.

CONCLUSION

20. The Inspira settlement provides for an exceptional outcome for creditors and NECC's estate. It provides \$16 million, without the costs, complexity, delay and ultimate uncertainty of litigation. The vast majority of the Inspira settlement amount will inure to the benefit of Inspira personal injury claimants holding allowed claims. In my opinion, the Inspira settlement is fair, reasonable, adequate and equitable and the interests of personal injury claimants is best served by approval of the Inspira settlement.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Dated: April 29, 2015

Michael F. Barrett, Esq.

PLAN PROPONENTS' EXHIBIT 2

UNITED STATES BANKRUPTCY COURT DISTRICT OF MASSACHUSETTS EASTERN DIVISION

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In re:	
NEW ENGLAND COMPOUNDING	Chapter 11
PHARMACY, INC.,	Case No. 12-19882-HJB
Debtor.	

DECLARATION OF KIMBERLY A. DOUGHERTY IN SUPPORT OF CONFIRMATION OF FIRST AMENDED JOINT CHAPTER 11 PLAN OF NEW ENGLAND COMPOUNDING PHARMACY, INC. AND FOR APPROVAL OF THE HIGH POINT SETTLEMENT

INTRODUCTION

- 1. My name is Kimberly A. Dougherty. I have personal knowledge of all matters set forth in this Declaration, except for those matters stated to be upon information and belief, and I believe all such matters to be true and correct. I am competent to testify under oath to the matters set forth in the Declaration if called to do so. I submit this Declaration in support of confirmation of the Joint Chapter 11 Plan of the New England Compounding Pharmacy, Inc. [Docket No. 1054] (as amended at Docket No. 1154 and thereafter, from time to time, and including all exhibits and supplements thereto, the "Plan") and, more specifically, as it relates to the settlement of claims against High Point Surgery Center ("High Point") and associated physicians relating to its purchase and administration of contaminated injections.
- 2. I am an attorney at the law firm Janet, Jenner & Suggs, LLC, in Boston, Massachusetts, and I have been an attorney in good standing in Massachusetts for over ten years. I have over ten years of experience representing consumers nationally against the manufacturers of dangerous pharmaceuticals and defective medical devices. I have tried multiple cases to verdict and I have resolved numerous mass tort litigations resulting in multi-million dollar settlements for our injured clients.
- 3. I have personal experience serving in leadership roles in other mass tort litigations. Currently, I serve in a leadership capacity in several litigations, including as court appointed co-Liaison Counsel for *In re: Tyco/Covidien Transvaginal Mesh Litigation*, Master Docket 12-03700-N (Middlesex Superior Court, Massachusetts) and *In re: Repliform Only Implant Cases*, Master Docket 13-5100-M (Middlesex Superior Court, Massachusetts). I also serve in a leadership capacity for *In re Specially Assigned Mesh Implant Cases*, Master Docket 11-3750M (Middlesex Superior Court, Massachusetts). In 2010, I was appointed by the court as

one of three Plaintiffs' Liaison/Lead Counsel for In re Reglan/Metoclopramide, Master Docket No. 1997 (Court of Common Pleas of Philadelphia County, Pennsylvania) as liaison for Plaintiffs' involved in litigation against the Patient Education Monograph Defendants. The cases are currently stayed pending appeal.

- 4. I am also the President of the Massachusetts Women's Bar Association and have been a Board member since 2009 and served on the Executive Committee since 2012. I am an Executive Board member and have been a Board of Governor of Massachusetts Academy of Trial Attorneys for several years and I was the Co-Chair of its Women's Caucus for the past eight years.
- 5. My firm has been involved in this litigation since its inception, filing our first case just 4 weeks after the nationwide recall. I attended hearings at the Massachusetts State Housing and read the testimony of several representatives from the Department of Public Health. I also represent approximately 100 individual personal injury and wrongful death claimants in this bankruptcy proceeding for claims arising from injections of contaminated methylprednisolone acetate ("MPA") compounded by New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC"). My clients include individuals who have died as a result of being administered contaminated MPA, as well as those who have developed fungal meningitis, other spinal fungal infections, arachnoiditis and complications from antifungal treatment.
- 6. From the beginning, I have taken a very active role in the In Re: New England Compounding Pharmacy ("NECP") litigation, including drafting pleadings and arguing multiple issues related to preservation orders and inspection of NECP's facility. Specifically, I briefed and argued in Massachusetts federal court on November 28, 2012, the adoption of the Honorable Judge Dennis Curran's Massachusetts state court preservation order and order of inspection of NECP's facility. I argued the issue of inspection on December 6, 2012 in front of Magistrate Boal and was successful in obtaining an order for a four day inspection of NECP's facility.
- 7. After the inspection was granted, I along with co-counsel Mark Zamora, took a lead role in drafting a protocol for the inspection with assistance from our experts. Concurrently, Attorney Zamora and I researched, interviewed and engaged multiple nationally recognized experts, including a forensic building expert, two clean room experts, a field hygienist and two laboratory hygienists, three HVAC specialists, and other assisting team members. We also took the lead negotiating with NECP, the government and GDC properties (the building owner) regarding the protocol for the inspection. Throughout this process we conferred with other plaintiffs lawyers regarding the selection of experts and the protocol.
- 8. During the four days of the inspection, I personally managed the inspection on three of the four days. This entailed being the point person for the dozens of plaintiffs visiting the facility and for all defense counsel and the government. It also involved negotiating sampling, destructive testing, removal of bulk samples, and other issues as they arose with the government, NECP and GDC Properties. I was also involved, along with other plaintiffs' lawyers, with providing NECP and GDC Properties notice of destructive testing and daily proposed plans for the next day's action items.

- 9. In April 2013, I was appointed to the Plaintiffs' Steering Committee ("PSC") for the *In re:*, *New England Compounding Pharmacy, Inc. Products Liability Litigation*, MDL No. 1:13-md-2419, pending in the United States District Court for the District of Massachusetts ("MDL").¹
- 10. Since the time of my appointment, I have continued to be heavily involved in the day to day litigation of the MDL cases. I have taken active roles in spearheading litigation against healthcare providers and on the matrix and science committee, liens committee, as well as serving as the PSC member mediating and negotiating with High Point and Victory Mechanical Services, Inc. and Victory Heating & Air Conditioning Co., Inc.
- 11. I have also appeared in front of this honorable court on behalf of the PSC to argue for fair and clear notice of the Bankruptcy and required Claim Form and PITWD addendum to victims.

HIGH POINT SETTLEMENT

- 12. High Point is a North Carolina health care provider that purchased and administered NECC's products to its patients, including contaminated MPA lots that were compounded by NECC during 2012. High Point was insured by Ironshore Specialty Insurance Company ("Ironshore") during the relevant time period. During the second half of 2014, High Point and Ironshore agreed to enter into the Mediation Program established by the MDL Court.
- 13. There are 22 individual claimants who filed proofs of claim against NECC in the Bankruptcy Court on the basis that they were administered one or more injections of NECC MPA at High Point. One claimant has already independently resolved claims against High Point. Of the remaining 21 claimants, 12 are represented by seven law firms (this number includes three claimants represented by my firm) and nine are unrepresented. This mediation did not involve or include separate claims the claimants have made against NECC in the Bankruptcy Court by virtue of having filed Proofs of Claims.
- 14. In preparing for the mediation with High Point, I obtained and reviewed numerous High Point documents and NECC documents concerning High Point. I also researched and analyzed complex issues and theories related to High Point's potential liability. I drafted a mediation brief that addressed the liability and causation issues relevant to the cases against High Point. Other High Point Claimants' attorneys contributed to this drafting. Additionally, all High Point Claimants' attorneys gathered and shared detailed information regarding the types of injuries suffered and the expenses incurred by their clients with their consent. Redacted information regarding the injuries suffered by the unrepresented claimants was provided by Counsel for the OCC. Thus, counsel for the High Point Claimants had a detailed understanding of both High Point's potential liability and the scope of the injuries that were sustained by all High Point Claimants.
- 15. Prior to the mediation session, the parties exchanged among themselves confidential mediation statements outlining each side's positions on legal claims, injuries and

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¹ MDL Doc. 82.

defenses. Each side accordingly was enabled to proceed into mediation fully aware of each parties' position and the basis for same.

- 16. Also briefed by the parties and considered throughout the mediation process, was the range of injuries suffered by the 21 High Point Claimants. There was a substantial variance in degree of harm and duration of injury among the High Point Claimants. While there was some dispute over the diagnoses, Plaintiffs' took the position that out of the 21 High Point Claimants, five claimants suffered from fungal meningitis,² seven claimants suffered from epidural abscesses, steroid site infections or paraspinal infections and two claimants suffered a stroke.³ Eight of the claimants received potent anti-fungal medication that had terrible side effects and risks such as disturbing hallucinations, liver or kidney function impairment, rashes and skin eruptions, very painful light sensitivity and long-lasting cognitive impairment. Five claimants were required to undergo one or more painful lumbar puncture diagnostic/monitoring procedures as well as repeated MRI/CT's and blood tests.
- 17. On September 16, 2014, a mediation session was held in Boston, Massachusetts among myself and other High Point Claimants' attorneys, High Point and Ironshore. Carmen Reiss of Resolutions LLC was the mediator. The mediation was conducted pursuant to the MDL Court's Mediation Order dated August 15, 2013. The mediation began with presentations on liability and damages by myself and other High Point Claimants' attorneys to High Point and the mediator.
- 18. Under the mediator's auspices, the parties discussed at length the strengths and weaknesses of the liability case against High Point, with High Point and Ironshore strongly contesting that High Point Claimants would be able to prove that High Point breached the standard of care owed to individual claimants. It was recognized by all parties that 95% of the medical malpractice cases tried in North Carolina end in defense verdicts. The parties also discussed the likelihood of North Carolina's medical malpractice noneconomic damages statutory cap applying to claimants and as well as the effect it would have on potential verdicts. Specifically, High Point asserted that under North Carolina law the noneconomic damages component of a judgment could not exceed \$500,000 against all defendants and that the statutory cap would apply to all claims brought by all parties arising out of the same professional services. The mediator, at all times, was actively involved in the process, ably encouraging the parties to logically and rationally consider their positions, authorities and facts to facilitate movement and realistic bargaining on each side.
- 19. The mediation session concluded late in the evening on September 16, 2014, with the parties having reached an agreement on the essential financial terms of the High Point Settlement. While High Point maintains it was not legally liable, together with Ironshore, it nonetheless agreed to contribute \$3.5 million to the settlement fund in exchange for a non-debtor release and injunction providing protection against any claims and liability relating to NECC's compounded drugs. The High Point settlement is conditioned upon confirmation of a Plan that provides non-debtor or third party releases, both to contributors as well as certain parties who are not direct contributors. The scope of these releases is limited to claims arising from

³ One of the two claimants suffering a stroke was the same claimant who resolved her claim prior to mediation.

² One of the five who claimants suffered from fungal meningitis resolved her claim prior to the mediation.

contaminated NECC products. These releases will have to be approved by the Court at confirmation (the settlement agreements, by their terms, only become wholly effective upon confirmation of a plan containing such releases). These non-party third party releases are a critical component of the High Point settlement, particularly with respect to persons and entities who are not directly contributing funds as part of this settlement.

- 20. While the financial terms of the settlement had been agreed upon, negotiations continued between myself and other High Point Plaintiffs' attorneys, the Trustee, counsel for the Creditors' Committee, High Point and Ironshore for many months over the terms and wording of the High Point Settlement Agreement. Detailed information was provided to our clients regarding the issues and obstacles. On information and belief, my colleagues did the same with regard to their respective clients. The agreement was finalized and executed on December 3, 2014.
- 21. Following the mediation and while the High Point Settlement Agreement was being prepared and finalized, I along with other High Point Plaintiffs' attorneys, the Trustee, counsel for the Creditors' Committee and the PSC met and conferred on numerous occasions to develop and agree upon a claims resolution process and distribution matrix for the portion of the High Point Settlement specifically earmarked for allocation to claimants administered contaminated NECC drugs at High Point. After much thought and deliberation, we all agreed that the Plan's matrix should serve as the base for distribution with a supplemental matrix to provide compensation reflecting the experience and situation of the High Point Claimants sharing this allocated fund. Therefore, the High Point supplemental claims resolution process and distribution matrix was developed to be used in combination with the proposed Chapter Plan's Tort Trust's claims resolution facility and Distribution Matrix. The process of reaching agreement was consensus driven and reflects the input and efforts of numerous High Point Plaintiffs' attorneys, counsel for the Creditors' Committee and members of the PSC.
- 22. As part of developing the proposed High Point supplemental claims resolution process and distribution matrix, claims administrators submitted proposals and were interviewed on their knowledge, experience and ability to serve as the High Point Claims Administrator. On the basis of these interviews and proposals, Edgar C. Gentle, III, Esq. of the firm Gentle, Turner, Sexton & Harbison, was selected to serve as the High Point Claims Administrator. The High Point supplemental claims resolution process includes a Facilitator to assist the pro se claimants with the process and submission of their claim forms. All of the decisions relating to the High Point supplemental claims resolution process and distribution matrix and the claim administrator were made by consensus, after thoughtful consideration and analysis. I believe they are all fair, reasonable, adequate and equable measures and should be approved by the Court as part of the Plan.

CONCLUSION

23. The High Point settlement of \$3.5 million provides for a fair and reasonable outcome for the creditors, NECC's estate and High Point, with the vast majority of the High Point settlement amount properly benefiting the High Point Claimants. I believe that the High Point settlement provides a greater recovery to NECC's bankruptcy estate and its creditors than what is likely through litigation, and without the costs, complexity, delay and ultimate

uncertainty of litigation. In reaching this conclusion, I have taken into account the variance in degree of harm and duration of injuries of all the High Point Claimants as well as the likelihood that North Carolina medical malpractice statutory law would apply. In my opinion, under the foregoing circumstances, along with other facts and circumstances that I anticipate will be presented to the Court, the High Point Settlement Agreement is a fair reasonable outcome for the High Point Claimants.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Dated: April 28, 2015

By:

Kimberly A. Dougherty Janet, Jenner & Suggs, LLC

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PLAN PROPONENTS' EXHIBIT 3

UNITED STATES BANKRUPTCY COURT DISTRICT OF MASSACHUSETTS EASTERN DIVISION

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NEW ENGLAND COMPOUNDING PHARMACY, INC.,

Chapter 11

Case No. 12-19882-HJB

Debtor.

DECLARATION OF KIMBERLY A. DOUGHERTY IN SUPPORT OF CONFIRMATION OF FIRST AMENDED JOINT CHAPTER 11 PLAN OF NEW ENGLAND COMPOUNDING PHARMACY, INC. AND FOR APPROVAL OF THE VICTORY SETTLEMENT

INTRODUCTION

- 1. My name is Kimberly A. Dougherty. I have personal knowledge of all matters set forth in this Declaration, except for those matters stated to be upon information and belief, and I believe all such matters to be true and correct. I am competent to testify under oath to the matters set forth in the Declaration if called to do so. I submit this Declaration in support of confirmation of the Joint Chapter 11 Plan of the New England Compounding Pharmacy, Inc. [Docket No. 1054] (as amended at Docket No. 1154 and thereafter, from time to time, and including all exhibits and supplements thereto, the "Plan") and, more specifically, in support of approval of the Victory Settlement.
- 2. I am a partner at the law firm Janet, Jenner & Suggs, LLC, and managing attorney of the Boston, Massachusetts office. I have been an attorney in good standing in Massachusetts since 2003. I have over 10 years of experience representing consumers nationally against the manufacturers of dangerous pharmaceuticals and defective medical devices. I have tried multiple cases to verdict and I have resolved numerous mass tort litigations resulting in multimillion dollar settlements for our injured clients.

- 3. I have personal experience serving in leadership roles in other mass tort litigations. Currently, I serve in a leadership capacity in several litigations, including as court appointed co-Liaison Counsel for *In re: Tyco/Covidien Transvaginal Mesh Litigation*, Master Docket 12-03700-N (Middlesex Superior Court, Massachusetts) and *In re: Repliform Only Implant Cases*, Master Docket 13-5100-M (Middlesex Superior Court, Massachusetts). I also serve in a leadership capacity for *In re Specially Assigned Mesh Implant Cases*, Master Docket 11-3750M (Middlesex Superior Court, Massachusetts). In 2010, I was appointed by the court as one of three Plaintiffs' Liaison/Lead Counsel for In re Reglan/Metoclopramide, Master Docket No. 1997 (Court of Common Pleas of Philadelphia County, Pennsylvania) as liaison for Plaintiffs' involved in litigation against the Patient Education Monograph Defendants.
- 4. I am also the President of the Massachusetts Women's Bar Association (WBA) and have been a Board member since 2009 and served on the Executive Committee since 2012. I am an Executive Board member and have been a Board of Governor of Massachusetts Academy of Trial Attorneys (MATA) for several years and I was the Co-Chair of its Women's Caucus for the past eight years.
- 5. My firm has been involved in this litigation since its inception, filing our first case just 4 weeks after the nationwide recall. I attended hearings at the Massachusetts State House and read the testimony of several representatives from the Department of Public Health. I also represent approximately 100 individual personal injury and wrongful death claimants in this bankruptcy proceeding for claims arising from injections of contaminated methylprednisolone acetate ("MPA) compounded by New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC"). My clients include individuals who have died as a result of being administered contaminated MPA, as well as those who have developed fungal meningitis, other spinal fungal infections, arachnoiditis and complications from antifungal treatment.
- 6. From the beginning, I have taken a very active role in the In Re: New England Compounding Pharmacy ("NECP") litigation, including drafting pleadings and arguing multiple issues related to preservation orders and inspection of NECP's facility. Specifically, I briefed and argued in Massachusetts federal court on November 28, 2012, the adoption of the Honorable Judge Dennis Curran's Massachusetts state court preservation order and order of inspection of

NECP's facility. I argued the issue of inspection on December 6, 2012 in front of Magistrate Boal and was successful in obtaining an order for a four day inspection of NECP's facility.

- 7. After the inspection was granted, I along with co-counsel Mark Zamora, took a lead role in drafting a protocol for the inspection with assistance from our experts. Concurrently, Attorney Zamora and I researched, interviewed and engaged multiple nationally recognized experts, including a forensic building expert, two clean room experts, a field hygienist and two laboratory hygienists, three HVAC specialists, and other assisting team members. We also took the lead negotiating with NECP, the government and GDC properties (the building owner) regarding the protocol for the inspection. Throughout this process we conferred with other plaintiffs lawyers regarding the selection of experts and the protocol.
- 8. During the four days of the inspection, I personally managed the inspection on three of the four days. This entailed being the point person for the dozens of plaintiffs visiting the facility and for all defense counsel and the government. It also involved negotiating sampling, destructive testing, removal of bulk samples, and other issues as they arose with the government, NECP and GDC Properties. I was also involved, along with other plaintiffs' lawyers, with providing NECP and GDC Properties notice of destructive testing and daily proposed plans for the next day's action items.
- 9. In April 2013, I was appointed to the Plaintiffs' Steering Committee ("PSC") for the *In re:*, *New England Compounding Pharmacy, Inc. Products Liability Litigation*, MDL No. 1:13-md-2419, pending in the United States District Court for the District of Massachusetts ("MDL").
- 10. Since the time of my appointment, I have continued to be heavily involved in the day to day litigation of the MDL cases. I have taken active roles in spearheading litigation against healthcare providers and on the matrix and science committee, liens committee, as well as serving as the PSC member mediating and negotiating with Victory and a clinic and hospital in North Carolina.

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¹ MDL Doc. 82.

11. I have also appeared in front of this honorable court on behalf of the PSC to argue for fair and clear notice of the Bankruptcy and required Claim Form and PITWD addendum to victims.

VICTORY SETTLEMENT

- 12. Victory Mechanical Services, Inc. and Victory Heating & Air Conditioning Co., Inc. (collectively "Victory") is a Massachusetts corporation with its principal place of business in Bellingham, Massachusetts. Victory designed and installed the HVAC systems for the cleanrooms at NECC's facility, in which the three contaminated MPA lots were compounded. Also, Victory serviced and maintained the HVAC system at NECC, including years prior to and continuing through and after the outbreak.
- 13. At all relevant times, Victory was insured by The Netherlands Insurance Company and Peerless Insurance (collectively "Insurers").
- 14. The PSC intended to set forth allegations against Victory in the Master Complaint; however, Victory entered into the MDL Court's mediation program, pursuant to the MDL Court's Mediation Order dated August 15, 2013, prior to being named in claims by hundreds of plaintiffs.
- 15. In preparation for the Victory mediation, I reviewed numerous documents produced by Victory and NECC documents obtained from the Trustee that pertain to Victory. On behalf of the PSC, and for the mutual benefit of the PSC, the OCC and the Trustee, I retained several consultants with expertise in the areas of engineering, HVAC engineering and cleanroom design. I drafted a mediation brief that addressed the liability and causation issues relevant to the case against Victory. Victory also drafted a mediation brief, addressing their defenses. Each party had the opportunity to review the mediation briefs in advance of the mediation, providing opportunity to prepare for it.
- 16. The mediation sessions with Victory were held on July 21 and July 23, 2014 in Boston, Massachusetts. Participants of the mediation included myself (as Designated Counsel representing the PSC), the Trustee, Counsel for the Creditors' Committee, Victory, and Insurers. Carmen Reiss of Resolutions LLC acted as mediator.

- 17. Victory strongly contested that Plaintiffs contentions, claiming the PSC would be unable to prove that Victory negligently designed and/or installed the HVAC system and that it had a duty to maintain and service NECC's HVAC system for years prior to and during the time relevant to the outbreak. More specifically, Victory asserted, among other things, it did not: (a) design, install or maintain the fan filter boxes and HEPA filters in the ceiling of the cleanrooms where openings were found that would allow contaminants to fall into the cleanroom;2 and (b) have a maintenance agreement with NECC to service the HVAC system of the cleanrooms during the time the contaminated products were compounded.3
- 18. Of great contention was the finding of exserohilum rostratum and aspergillus fumigatus⁴ within the HVAC system. The Plaintiffs contended that the negligent design of the HVAC system pulling outside air from a location directly adjacent to a recycling factory lead to these fungi entering the cleanroom through the HVAC system. Victory claimed that the finding of the fungi in the HVAC system showed that it was working and collecting the contaminants before they entered the cleanroom, insisting that the contaminants entered on NECC personnel or others' bodies that entered the cleanroom.
- 19. Victory also vehemently argued that the PSC could not prove that its actions caused the victims injuries. Victory contended that even if it had been negligent in some way, ultimately, the negligence of others broke the causal chain between its negligence and the injuries of the Plaintiffs.
- 20. There was also a dispute over whether Victory's insurance policy limit under Insurers totaled \$7 million for the relevant policy period.
- 21. On July 23, 2014, the mediation concluded and the parties reached an agreement on the essential financial terms, pursuant to which Victory and Insurers would contribute \$5.5

² Victory contends that because it was not responsible for the fan filter boxes and HEPA filters for the cleanrooms its employees never conducted any work or inspected above the cleanrooms after the initial installation of the HVAC system. Therefore, Victory claims that it could not have been responsible for or aware of the gaps between the fan filter boxes and ceiling tiles of the cleanrooms, the debris above the cleanrooms and the holes in the ductwork that supplied air to the cleanrooms, contending those events occurred after its installation.

³ Victory contends that it only had a maintenance agreement with NECC for one of the cleanrooms from 2007 to 2009, and that even if they did have an obligation to service the HVAC system thereafter, that NECC would not cooperate to allow servicing and entrance into the facility.

⁴ Exserohilum rostratum and aspergillus fumigates were the fungi found in the contaminated recalled vials of NECC's MPA and the spines of many victims who contracted fungal meningitis.

million to the settlement fund.

22. While the financial terms of the settlement had been agreed upon, negotiations continued between myself, the Trustee, counsel for the Creditors' Committee, Victory and Insurers for many months over the terms and wording of the Victory Settlement Agreement. The agreement was finalized and executed on November 11, 2014.

THE REASONABLENESS OF THE VICTORY SETTLEMENT

- 23. The plan of reorganization (the "Plan") involves numerous settlements of various disputes between and among the NECC estate, certain of NECC's contractors and their insurance companies, various clinics/ hospitals that administered contaminated MPA and personal injury claimants. If approved by the Court, the Plan will provide the NECC bankruptcy estate with approximately \$200 million \$5.5 million of this amount will be contributed by Victory and its Insurers. Upon approval of the Plan, and after payment of allowed administrative expenses, assets of the NECC estate will satisfy the claims held by creditors, the majority of which are comprised of personal injury claimants.
- 24. I believe the Victory settlement is fair and provides for greater recovery to NECC's bankruptcy estate and its creditors than would be likely after litigation, without the corresponding delay, expense and risks associated with such litigation. After weighing the value of the claims being compromised against the value of the Victory settlement to the NECC bankruptcy estate and its creditors I have determined that the Victory settlement is reasonable for the following reasons:

The Risks of Litigation

- 25. An important factor in evaluating whether the proposed Victory settlement is in the best interests of the NECC bankruptcy estate and its creditors is the probability of success in litigation. While I and members of the PSC believe that Victory's negligence could ultimately be proven, success against Victory in litigation is far from certain.
- 26. Although I believe Victory's contentions that it did not have a duty to design, install and service the cleanroom HVAC system, and, even if it did, that it did not negligently

perform such duties were surmountable, Victory presented credible arguments and defenses as to causation that were briefly addressed above and will be more fully explored here.

- 27. Victory asserted that if exserohilum rostratum and aspergillus fumigates were found on the air intake filters it would show that the filters were functioning appropriately and capturing the fungi from the outside air before it could circulate through the HVAC system. Moreover, Victory claimed that the filter the PSC's expert did find spores of the fungi on was not an air intake filter but a mixed air filter. According to Victory, fresh air and return air from the cleanroom is funneled through the mixed air filter making the cleanroom itself a potential source of the fungal spores found in the mixed air filter. Victory also asserted that it did not install the HEPA filters adjacent to the areas where the aspergillus fumigates was located and that another party was responsible for the gap between the HEPA filter and the cleanroom ceiling.
- 28. During the four day inspection of NECC, the PSC and their experts' ability to take samples were negotiated with NECC, GDC and specifically, and strictly, curtailed by the Federal Bureau of Investigation ("FBI") who were present during the investigation. The PSC's experts were only permitted to take limited samples due to time constraints to complete a facility wide inspection and were also limited in their ability to remove samples from filters, ceiling tiles, walls and other locations given the strict oversight by the FBI. In order to prove that Victory's negligence proximately caused the injuries to the victims with more than somewhat circumstantial evidence, it would be necessary to have an expert thoroughly examine and test multiple samples from NECC's entire cleanroom HVAC system. However, it has been approximately two and one-half years since NECC has ceased operations, making the probative value of any evidence found in the HVAC system uncertain at best.
- 29. Furthermore, discovery of Liberty, NECC and its employees would also be necessary to establish the negligence claimed by the PSC, including which entity designed the air intake, which actually installed the HEPA filters, and which controlled the pressurization in the cleanroom (potentially responsible for putting holes in the HVAC system), etc. all of which Victory vehemently claimed it did not do and that discovery was not available at the time of mediation and would have been extremely costly to perform, if able to at all given NECC is likely to plead the 5th because of the criminal actions pending against them.

- 30. Another challenge the Plaintiffs faced was establishing that the casual chain between any potential negligence claimed of Victory was not broken later by acts of negligence by other parties, including Liberty, NECC, Unifirst and the hospitals and healthcare providers that performed the injections.
- 31. While I recognize that the creditors that hold claims, including the personal injury claimants, for the NECC bankruptcy estate have meaningful claims against Victory, I also appreciate that litigation is inherently risky and after evaluating all liability factors, I believe that the Victory settlement is reasonable, fair and adequate.

Complexity, Expense, Inconvenience and Delay in Pursuing Litigation

32. I reasonably anticipate that litigation of the claims against Victory would be lengthy, complex and expensive. Likely, Victory would vigorously deny liability, reducing the amount of available insurance coverage, and protracting any resolution of the claims against them. Moreover, costly discovery would have been required of other entities, including NECC, Liberty and Unifirst to establish certain theories of liability. Many of the personal injury claimants have already waited over two and one-half years for compensation and are suffering substantial financial hardship as a result of the injuries caused by the contaminated MPA. I believe that that the Victory settlement is in the best interest of the NECC bankruptcy estate.

Issues with Collectability

33. Victory is a Massachusetts, privately held company with minimal assets as it relates to the claims held by the plaintiffs. While a declaratory judgement action seeking to decline insurance coverage was not filed by its insurer, the reality of such was real given the claims made by the PSC. If such an action was filed and successful, Victory has limited assets to cover the claims of the Plaintiffs.

Third Party Releases are a Necessary Requirement for the Victory Settlement

34. The Plan, if approved by the Court, will provide third party releases to contributors of the NECC bankruptcy estate as well as certain parties who are not direct contributors. The scope of these releases is limited to claims arising from contaminated NECC products. Upon the Court's confirmation of the Plan and the releases, the settlement agreements, including the Victory settlement, will become wholly effective. Based on my personal

involvement in the mediation with Victory and their Insurers and my participation in the settlement negotiations that followed, I understand that the third party releases were a crucial requirement of the Victory settlement, and that absent the releases, Victory would not have offered the \$5.5 million.

35. As previously noted, it is anticipated that the majority of the claims against the NECC bankruptcy estate are held by personal injury claimants. Therefore, under the terms of the Bankruptcy Code and the contemplated Chapter 11 plan, after the payment of allowed administrative expenses the net proceeds of the NECC bankruptcy estate, including Victory's contribution, would be distributed to the tort claimants. Indeed, I believe that distribution under the Plan will provide the most equitable outcome for the all claimants, including the personal injury claimants, when considering that the alternative of litigation would likely only allow few, if any, of the victims to recover for their injuries.

CONCLUSION

36. The Victory settlement of \$5.5 million provides for a fair and reasonable outcome for creditors, NECC's estate and Victory. I believe that the Victory settlement provides a greater recovery to NECC's bankruptcy estate and its creditors than what is likely through litigation, and without the costs, complexity, delay and ultimate uncertainty of litigation. In my opinion, under the foregoing circumstances, along with other facts and circumstances that I anticipate will be presented to the Court, the Victory Settlement agreement is a fair reasonable outcome for the NECC bankruptcy estate.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Dated: April 28, 2015

By:

Kimberly A. Dougherty Janet, Jenner & Suggs, LLC 31 St. James Ave., Suite 365

Boston, MA 02116

kdougherty@myadvocates.com

(617) 933-1265

PLAN PROPONENTS' EXHIBIT 4

UNITED STATES BANKRUPTCY COURT DISTRICT OF MASSACHUSETTS EASTERN DIVISION

In re:

NEW ENGLAND COMPOUNDING PHARMACY, INC.,

Debtor.

Chapter 11

Case No. 12-19882-HJB

DECLARATION OF FREDRIC L. ELLIS IN SUPPORT OF CONFIRMATION OF FIRST AMENDED JOINT CHAPTER 11 PLAN OF NEW ENGLAND COMPOUNDING PHARMACY, INC. AND FOR APPROVAL OF ARL SETTLEMENT

INTRODUCTION

- 1. My name is Fredric L. Ellis. I have personal knowledge of all matters set forth in this Declaration, except for those matters stated to be upon information and belief, and I believe all such matters to be true and correct. I am competent to testify under oath to the matters set forth in the Declaration if called to do so. I submit this Declaration in support of confirmation of the Joint Chapter 11 Plan of the New England Compounding Pharmacy, Inc. [Docket No. 1054] (as amended at Docket No. 1154 and thereafter, from time to time, and including all exhibits and supplements thereto, the "Plan") and, more specifically, in support of approval of the ARL Settlement.
- 2. I have been an attorney in good standing in Massachusetts for over thirty years. I graduated with honors from Harvard Law School in 1983. From 1983 to 1984, I was a law clerk to Justice Raya S. Dreben of the Massachusetts Appeals Court. From 1984 to 1986, I served as an Assistant District Attorney in the Middlesex County District Attorney's Office, trying cases in the District and Superior Courts and briefing and arguing cases in the Massachusetts appellate courts, including first-degree murder cases in the Massachusetts Supreme Judicial Court. In 1986, I was appointed Deputy-Chief of the Appeals and Training Bureau for the Middlesex District Attorney's Office, supervising eleven attorneys in all aspects of appellate litigation.
- 3. From 1988 to 1996, I was in private practice at the Boston law firm of Gilman, McLaughlin & Hanrahan, where I was made a partner in 1991. I handled a variety of civil and criminal cases, including business litigation, products liability and class actions. In 1992, I was appointed to several plaintiffs' counsel committees in the Silicone Gel Breast Implant Product Liability Litigation, MDL-926, and was later appointed by Judge Sam Pointer of the Federal District Court in the Northern District of Alabama to serve on the MDL-926 Common Fund Disbursement Advisory Committee, which recommended appropriate attorney fee payments to

attorneys for common benefit work in that litigation. The silicone gel breast implant litigation involved hundreds of thousands of claimants and over twenty defendants, with tens of thousands of individual cases filed in state and federal courts throughout the country. Several of the defendants filed for bankruptcy and there were also a number of limited fund settlements, all coordinated with the MDL proceedings. I had substantial involvement with all of these various proceedings for many years, including oversight of the claims processes established to distribute several settlement funds.

- 4. In 1995, I was co-counsel for plaintiffs in the trial of <u>Toole v. Baxter Healthcare</u>, a breast implant case tried in Birmingham, Alabama, which resulted in a plaintiff's verdict of \$6 million, later reduced to \$1 million on remittitur. <u>See Toole v. Baxter Healthcare Corp.</u>, 235 F. 3d 1307 (11th Cir. 2000). I was also lead trial counsel and lead appellate counsel in <u>Mahlum v. Dow Chemical Co.</u>, in Reno, Nevada, which resulted in a \$14.15 million dollar plaintiff's verdict in October 1995, which verdict was partially affirmed on appeal. <u>See Mahlum v. Dow Chemical Company</u>, 114 Nev. 1468 (1998) reh'g denied, 115 Nev. 13 (1999). I was also lead trial counsel and lead appellate counsel in a breast implant case in Massachusetts, which resulted in a \$1.1 million plaintiff's verdict in 1996, which verdict was upheld on appeal. <u>Vassallo v. Baxter Healthcare Corp.</u>, 428 Mass. 1 (1998). In May 1996, I founded the firm of Ellis & Rapacki LLP. In the late 1990s, I settled over one hundred individual breast implant cases with breast implant manufacturers. I also negotiated a settlement with the U.S. Department of Health and Human Services to resolve the government's Medicare and Medicaid reimbursement claims against breast implant manufacturers and claimants.
- 5. I also served as lead counsel of the Plaintiffs' Steering Committee in several bankruptcy debtor reaffirmation class actions, including <u>In re: GECC Bankruptcy Reaffirmation Agreements Litigation</u>, MDL-1192. I was also co-lead class counsel in <u>Roberts v. Bausch & Lomb</u>, in the Northern District of Alabama, a nationwide consumer class action, and <u>Mohan v. Dell, Inc.</u>, in the San Francisco Superior Court, a California class action.
- 6. I have also served as lead class counsel in numerous other class actions, including Feiss v. MediaOne Group, U.S.D.C. N.D. Ga., Ciardi v. F. Hoffmann LaRoche, Mass. Sup. Ct., Sweeney v. BASF Corp., Mass. Sup. Ct., Providence Steel v. Union Central Life Insurance Co., U.S.D.C. D. Mass, and Shabshelowitz v. Royal Maccabees Life Insurance Co., U.S.D.C. D. Mass.
- 7. I have obtained numerous other jury verdicts and million dollar settlements in a wide range of other individual personal injury and wrongful death cases.
- 8. In 2005, I was appointed by Judge Denise Page Hood of the Federal District Court in the Eastern District of Michigan as Liaison Counsel for over 600 breast implant plaintiffs who opted-out of the Dow Corning Settlement Program in the Dow Corning Bankruptcy. I continue to serve in that role in coordinating the remainder of these cases in the Dow Corning Bankruptcy proceedings. More information concerning me and the Ellis & Rapacki LLP law firm may be found at www.ellisrapacki.com.
- 9. Since October of 2012, I have represented a number of clients with personal injury claims arising from injections of contaminated methylprednisolone acetate ("MPA)

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compounded by New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC"), and I filed one of the first cases involving NECC's products in Massachusetts state court in mid-October 2012. My clients include George Cary, individually and as the personal representative of the Estate of his wife, Lilian Cary, who died as a result of being administered contaminated MPA. Mr. Cary, who also received MPA injections, was diagnosed with fungal meningitis. Other clients of mine include those who developed fungal meningitis and other spinal fungal infections.

- 10. I was among the attorneys who coordinated the inspection of NECC's premises in December 2012, and was responsible for administering the fund established by plaintiffs' firms to conduct the inspection. I assisted in drafting the protocol for the inspection and I also coordinated the scheduling of plaintiffs' firms from around the country to visit the site during the four-day inspection.
- 11. I was the first attorney to name NECC's outside testing laboratory, ARL Bio Parma, Inc. ("ARL"), as a defendant in any case in the country. The complaint against ARL alleged that ARL was negligent in allowing NECC to submit an inadequate number of samples for sterility testing¹, which practice did not comply with the United States Pharmacopeia ("USP"). ² Specifically, USP chapter <71> ("USP 71"), which governs sterility testing, requires a certain number of samples to be tested in order to ensure valid sterility test results. For example, in a batch of parenteral preparation³ of more than 500 articles, the minimum number of articles that must be tested is twenty. The complaint alleged that ARL was negligent in certifying as sterile three lots of contaminated MPA produced by NECC, each of which consists of more than 5,000 vials, based on testing of only two (2) vials from each lot, and that the negligence of ARL was a proximate cause of the plaintiff's injuries.
- 12. In February 2012, I assisted the Creditors' Committee's counsel in the preliminary injunction hearing before this Court, which resulted in the issuance of injunctions, attachments and trustee process over the assets of several NECC's officers and directors (the "NECC Insiders").
- 13. In 2013, as a result of discovery requests propounded by my firm in state court cases, I obtained and reviewed over 28,000 pages of ARL documents. I have worked hand-in-hand with the Plaintiffs' Steering Committee ("PSC") since the nascent stages of the MDL. I am the PSC's designated counsel responsible for a number of areas, including litigating against and ultimately negotiating the settlement with ARL on the PSC's behalf. On September 20, 2013, ARL elected to participate in the MDL Court's mediation program.
- 14. I am familiar with the requirements for approval of settlements in bankruptcy proceedings as prescribed in <u>Protective Committee for Independent Stockholders of TMT Trailer</u> Ferry, Inc. v. Anderson, 390 U.S. 414, 424-45 (1968), and Jeffrey v. Desmond, 70 F. 3d 183 (1st

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¹ Sterility testing is used to screen drugs for the presence of bacteria, fungi, and other microorganisms.

² The United States Pharmacopeia ("USP") is a scientific non-profit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements.

³ A "parenteral preparation" refers to an injectable medication, such as MPA.

Cir. 1995). I submit this Declaration to set forth the facts demonstrating that consideration of the factors in those cases (the "TMT/Jeffrey Factors") weighs heavily in favor of approval of the ARL Settlement.

BACKGROUND MATTERS

A. ARL and Its Insurer

- 15. ARL is an Oklahoma corporation with a principal place of business in Oklahoma City, Oklahoma. For a number of years prior to and including 2012, ARL conducted sterility testing on NECC's products, including the three contaminated MPA lots that were compounded by NECC during 2012.
- 16. Upon information and belief, by the fall of 2013, hundreds of lawsuits in federal and state courts throughout the country named ARL as a defendant. Many of those cases were later transferred to the MDL Court whether by the Judicial Panel on Multidistrict Litigation or operation of transfer orders entered by the MDL court.
- 17. Absent a prompt, global resolution of those numerous competing claims, any amounts available to compensate personal injury claimants likely would have been exhausted in a race to the courthouse. In contrast, a prompt global resolution with ARL through the NECC estate would ensure that available proceeds were equitably distributed among those who were injured or died as a result of the contaminated MPA lots.
- On May 31, 2013, ARL's insurance company, Landmark American Insurance Company ("Landmark") filed a petition Oklahoma state court seeking a declaratory judgment concerning the scope of an insurance policy issued by it to ARL for the period from October 1, 2011 through October 1, 2012. A copy of the Landmark Petition is attached hereto as Exhibit 1. The petition sought a declaration that (i) "the claims asserted in the underlying lawsuits, and all other claims asserted against ARL for injuries, arise out of a series of related, allegedly negligent acts, errors, or omissions and are therefore treated as a single claim," and (ii) because [the claims] are treated as a single claim, [the] \$3,000,000 claim limit, and not the \$6,000,000 aggregate limit applies to satisfy all claims or asserted claims against ARL arising from the underlying event[.]" Id., Ex. 1 at § 13. On January 23, 2014, after ARL filed an answer to the Landmark Petition, the court granted the PSC's motion to intervene in the declaratory judgment action and the PSC filed an Answer to the Landmark Petition.

B. Settlement Negotiations with ARL

- 19. In preparing for the mediation with ARL, I also obtained from the Trustee and reviewed numerous NECC documents concerning ARL.
- 20. My preparation for the ARL mediation spanned many months and focused on many complex issues and theories. On behalf of the PSC, and for the mutual benefit of the PSC, the OCC, and the Trustee, I retained a consultant who has extensive expertise in microbiology to review some of the relevant documents and to assist in preparing a mediation brief outlining

ARL's potential liability. I also devoted substantial time and effort in my investigation of the financial condition of ARL and its available assets.

- 21. In March 2014, I drafted a mediation brief that addressed the liability and causation issues relevant to the cases against ARL, as well as a separate brief addressing the insurance coverage issue raised by the Landmark Petition. The OCC and the Trustee contributed to this drafting.
- 22. On April 1 and 2, 2014, mediation sessions were held in Boston among myself (as Designated Counsel representing the PSC), the Trustee, Counsel for the Creditors' Committee, one of the attorneys representing one of the members of the Creditors' Committee, ARL, and Landmark. Carmen Reiss, Esq. of Resolutions LLC was the mediator. The mediation was conducted pursuant to the MDL Court's Mediation Order dated August 15, 2013.
- 23. ARL's and Landmark's primary defenses were that Plaintiffs would not be able to prove that: (i) ARL tested any final product⁴ from any of the three contaminated lots of MPA; (ii) any testing conducted by ARL yielded an inaccurate result; and (iii) that any act or omission by ARL caused damage to any individual claimant. As for insurance coverage, Landmark's position was that the \$3 million claim limit applied, and that, pursuant to the policy, the claim limit was reduced by defense costs that had been incurred by Landmark between October 2012 and March 2014.
- 24. The settlement negotiations were at all times contentious, hard fought and conducted on an arms-length basis.
- 25. The mediation session concluded during the evening of April 2, 2014, with the parties having reached an agreement on the essential financial terms pursuant to which ARL and Landmark would contribute \$6.4 million to the settlement fund.
- 26. While the financial terms of the settlement had been agreed upon, negotiations continued among myself, the Trustee, counsel for the Creditors' Committee, ARL, and Landmark for many months over the terms and wording of the ARL Settlement Agreement. The agreement was finalized and executed on December 4, 2014.

THE REASONABLENESS OF THE ARL SETTLEMENT

27. The proposed Plan⁵ contemplates court approval of numerous settlements of various disputes between and among the NECC estate, certain of NECC's contractors and their insurance companies, various clinics/ hospitals that administered contaminated MPA and personal injury claimants. If allowed, the plan of reorganization (the "Plan") will provide the

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⁴ ARL contended that the 5 mL vials of MPA submitted to it for testing from the three contaminated lots of MPA were taken from each respective batch before the filling of vials for release and it was likely that any contamination occurred during the fill process. Thus, according to ARL, even if it was negligent in conducting the sterility testing, which ARL disputed, it would not have discovered any contamination as the vials sent for testing were not contaminated.

⁵ Terms used herein have the same definitions as defined in the Plan and/or the Tort Trust Agreement.

NECC estate with an amount projected to be approximately \$200 million. Of this amount, \$6.4 million will be contributed by ARL and its insurer.

- 28. The ARL settlement proceeds, which have been placed into an escrow account, will become property of the NECC bankruptcy estate pursuant to a Chapter 11 plan. Personal injury claimants by far hold the majority of claims in NECC's bankruptcy case, and the Plan provides for payment of allowed claims from the assets of the NECC estate after payment of allowed administrative expenses. As the largest block of creditors anticipated to hold allowed claims, personal injury claimants (through the Tort Trust created by and set forth in the plan) will receive the largest portion of NECC's assets, including the proceeds of the ARL settlement.
 - 29. I believe that the ARL settlement is reasonable for at least the following reasons:
 - a. **Result**: In assessing and balancing the value of the claims being compromised against the value to the estate and its creditors by virtue of the proposed settlements, I believe the funds available from the settlement provide a greater recovery to NECC's bankruptcy estate and its creditors than would be likely after litigation, without the corresponding delay, expense and risks associated with any such litigation. Both ARL and ARL's insurer (who raised a serious coverage defense) are making a substantial contribution to the ARL settlement;
 - b. <u>Collectability</u>: ARL was founded in 1999 and is a small, privately held company with few assets. There is a serious question whether \$3 million or \$6 million in insurance coverage is available for <u>all</u> claims against ARL. The ARL insurance policy is also a wasting policy (i.e., defense costs are deducted from the policy limit), and I believe that, if there was no settlement, the policy limit would be eroded by defense costs. In such a situation, collecting judgments against ARL would be difficult. The ARL settlement results in significantly enhanced prospects for collection. A fixed sum of \$6.4 million has been deposited into an escrow account, which I believe is an amount that is more than could be secured were the NECC estate and personal injury claimants to succeed in litigation.
 - c. <u>Disputed Liability</u>: I believe the prospects for recovery against ARL in litigation are far from certain. While I believe that ARL's negligence would be proven, the issue of causation is more difficult. An inability to prove causation would raise serious issues that may defeat liability entirely. With respect to ARL's insurer, there exists a serious issue as to whether \$3 million of \$6 million of insurance coverage is available under the Landmark policy, creating significant doubts as to whether, when and to what extent insurance proceeds would be available for recovery by the NECC estate (or, indeed, any personal injury claimant) in litigation; and
 - d. <u>Plan Progress/Interests of Creditors</u>: Approval of the ARL Settlement is essential to the approval of the Chapter 11 plan, and, I believe, is in the best interest of the estate's creditors. The victims of the outbreak have already waited

for over two and one half years for compensation, and confirmation of the Plan will allow distributions from the Tort Trust to begin to be made to them.

A. The Probability of Success in Litigation

- 30. The first TMT/Jeffrey Factor to consider in evaluating whether the proposed ARL settlement is in the best interests of the estate and its creditors is the probability of success in litigation. This evaluation is necessary to assess and balance the value of the claims that are being compromised against the value to the estate by virtue of the proposed compromises.
- 31. In evaluating the estate's and its creditors' claims against ARL for damages resulting from the contaminated MPA lots, it is necessary to examine not only ARL's conduct in testing NECC's products, but also to consider ARL's defense that, even if NECC could prove negligence, ARL's negligence was not a proximate cause of the injuries suffered by any of the personal injury claimants. Because the samples of MPA that were sent to ARL for sterility testing were apparently not taken from the final product after the fill procedure, it is possible that the vials tested were, in fact, sterile, and that the contaminated vials of MPA distributed to clinics and hospitals were actually contaminated during the fill procedure. To rebut ARLs causation defense, experts would be required to engage in extensive forensic analyses of NECC's operations. In order to prove that ARL's negligence proximately caused the injuries to the victims, it would be necessary to retain experts who could testify as to what caused the adulteration of the MPA lots and when the contamination occurred. Proving that ARL acted negligently and that its negligence caused the injuries suffered by victims would not be simple, inexpensive, quick or convenient. Moreover, the losing party could appeal, leading to further delay, complexity and expense.
- 32. Moreover, to prevail against ARL, the NECC estate (and the personal injury claimants) might be in the anomalous position of relying upon the testimony of some of the NECC Insiders regarding NECC's course of dealing with ARL. This could pose difficulties as, upon information and belief, the NECC Insiders likely would assert their rights to withhold testimony under the Fifth Amendment to the United States Constitution, which could make obtaining a recovery against ARL all the more challenging. As time passes, it will also likely become more difficult to obtain reliable testimony concerning when and how the contamination occurred.
- 33. In sum, while I believe that the NECC estate (and personal injury claimants) have substantial claims against ARL, I am also mindful that litigation is inherently risky and that the difficulties summarized above make success in litigation far from certain. The ARL settlement essentially bypasses the liability concerns described above. Under the ARL settlement, ARL and its insurer are making a substantial contribution without regard to their potential defenses and without regard to the strength or weakness of the factors described above that, in the worst case for NECC and the personal injury claimants, might result in a finding in favor of ARL.

B. <u>Difficulties Encountered in the Matter of Collection</u>

34. Based on my investigations to date, ARL is a small, closely held business with few assets. As for ARL's insurance policy, it is by no means certain that it provides more than

\$3 million for all of the claims of the NECC estate and the personal injury claimants. Moreover, as the ARL insurance policy is a "wasting policy" (*i.e.*, defense costs are deducted from the policy limits) it is highly likely that the policy limits (whether \$3 million or \$6 million) would be eroded by defense costs in the ensuing litigation if a settlement is not approved. I believe that if the insurance policy were to be exhausted, collecting judgments against ARL's assets would be extremely difficult. Additionally, any coverage litigation with ARL's insurer would also be costly, difficult, complex and time consuming.

C. Complexity, Expense, Inconvenience and Delay in Pursuing Litigation

- 35. Upon information and belief, the litigation that would be required to be pursued if the ARL settlement is not approved would be complex and expensive. Moreover, any such litigation likely would be protracted, such that any recovery for the benefit of creditors would be significantly delayed. Absent settlement, ARL likely will vigorously contest liability until its insurance coverage is exhausted by defense costs, and it will then likely file for bankruptcy protection or simply cease to operate as a going concern.
- 36. I do not believe that it is in the best interest of the NECC estate or the personal injury claimants to pursue the complex, lengthy, and costly litigation that would be required if the ARL settlement is not approved. Many of the personal injury claimants are suffering substantial financial hardship as a result of the injuries caused by the contaminated MPA and they have a compelling need to secure a recovery as soon as possible. The proposed settlement will greatly enhance the likelihood of achieving that goal.

D. The Third Party Releases Were Necessary to Bring About the ARL Settlement

- 37. The contemplated ARL settlement is conditioned upon confirmation of a Plan that provides third party releases, both to contributors as well as certain parties who are not direct contributors. The scope of these releases is limited to claims arising from contaminated NECC products. These releases will have to be approved by the Court at confirmation (the settlement agreements, by their terms, become wholly effective only upon confirmation of a plan containing such releases). Upon information and belief, the third party releases are a critical component of the ARL settlement, particularly with respect to persons and entities who are not directly contributing funds as part of this settlement.
- 38. As a direct participant in the settlement negotiations, I understood that a channeling injunction and third party releases were the *sine qua non* for ARL's and its insurer's agreement to settle.
- 39. The benefits to the NECC estate from the ARL settlement (\$6.4 million), the majority of which will flow to the tort claimants, is a principal reason why the third party releases are reasonable. The proceeds of these settlements are not "earmarked" to any particular group or constituency. Rather, the proceeds will be paid to the NECC estate, and are property of the estate, to be distributed on account of allowed administrative expenses and allowed claims in accordance with the Bankruptcy Code and the terms of the contemplated Chapter 11 plan. Since it is anticipated that personal injury claimants will hold the vast majority of allowed claims, the vast majority of the net proceeds of the ARL settlement (after payment of allowed administrative

expenses and priority claims, if any) will be distributed to personal injury claimants. Moreover, the settlement funds will be distributed in a fair and equitable manner, rather than as a result of a race to the courthouse.

E. Paramount Interests of Creditors and a Proper Deference to Their Views

- 40. Personal injury claimants have suffered severe medical and financial harm, regardless of whether ARL is liable for damages. The ARL settlement, if allowed, will accelerate the progress of this case and provide a mechanism for prompt and meaningful payment to personal injury claimants holding allowed claims. Personal injury claimants have already waited too long for this case to be resolved. Approval of the ARL settlement will accelerate the pace of events necessary to occur to enable payment to such claimants and ameliorate the severe financial hardship some claimants are suffering from.
- 41. Perhaps the strongest indicator of creditor support for approval of the ARL settlement is that all of the Creditors' Committee, the PSC, and the Trustee support approval. The PSC and the Creditors' Committee have among them members and/or counsel who are sophisticated plaintiffs' personal injury counsel and both committees actively participated in the settlement negotiations with ARL and Landmark. That both representative bodies strongly support approval of the ARL settlement provides further validation and proof that the ARL settlement serves the paramount interests of creditors. A proper deference to their views weighs heavily in favor of approval of the ARL settlement.

CONCLUSION

42. The ARL settlement is an exceptional outcome for creditors and NECC's estate. The ARL settlement provides \$6.4 million, without the costs, complexity, delay and ultimate uncertainty of litigation. The vast majority of the ARL settlement amount will inure to the benefit of personal injury claimants holding allowed claims. In my opinion, the ARL settlement is fair and reasonable and the interests of personal injury claimants is best served by approval of the ARL settlement.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Dated: April 27, 2015

Fredric L. Ellis

EXHIBIT 1



(J 2013-3193 Swintm

IN THE DISTRICT COURT OF OKLAHO

LANDMARK AMERICAN) MAY 3/1 2013
INSURANCE COMPANY,) TIM RHODES COURT CLELK
Plaintiff,	2
vs.	GL No. 2013-3193
ARL BIO PHARMA, INC. D/B/A	Ś
ANALYTICAL RESEARCH)
LABORATORIES,)
)
Defendant.) *

PETITION FOR DECLARATORY JUDGMENT

COMES NOW Landmark American Insurance Company ("Landmark") and pursuant to 12 O.S. §1651, files this Petition for Declaratory Judgment and respectfully shows:

I.

THE PARTIES

- Plaintiff Landmark is an insurer organized under the laws of the State of 1. Oklahoma and having its principal place of business in Atlanta, Georgia.
- Defendant ARL Bio Pharma, Inc. d/b/a Analytical Research Laboratories ("ARL") is an Oklahoma corporation with its principal place of business a: 840 Research Parkway, Suite 546, Oklahoma City, Oklahoma.

П.

JURISDICTION AND VENUE

Jurisdiction and venue are proper in that Defendant ARL is an Oklahoma 3. corporation located in Oklahoma County, and ARL may be served by serving the registered agent for ARL, Thomas Kupiec, with service of process at 840 Research Parkway, Suite 546, Oklahoma City, Oklahoma.

 Further, this action concerns the interpretation of an insurance policy issued to ARL in Oklahoma.

III.

FACTUAL BACKGROUND

- 5. ARL provides laboratory testing services to compounding pharmacies, including the New England Compounding Pharmacy, Inc. ("NECP"). Between May and August 2012, NECP sent samples from three lots of methylpredisolone acetate ("the steroic") to ARL for sterility testing. The steroid is used to treat back pain and is received by patients through an epidural injection. Following testing of the samples from the first two lots, ARL reported the samples were "sterile." A vial from the third lot, however, showed heavy fungal growth after an incubation period. NECP recalled the third lot in September 2012.
- 6. Hundreds of individuals have reportedly contracted fungal meningitis after being injected with the steroid ("the underlying event"). As a result, several lawsuits were filed nationwide naming NECP and ARL as defendants, among others (the "underlying lawsuits"). The United States Judicial Panel on Multi-District Litigation issued an order on February of 2013 transferring the underlying lawsuits to the United States District Court in the District of Massachusetts.
- Plaintiffs in the underlying lawsuits generally allege that ARL was negligent in the manner in which it conducted sterility testing on the steroid samples provided by NECP.

- 8. Landmark issued a professional liability policy to ARL, policy number LHM731509, effective October 1, 2011 to October 1, 2012. The policy has a \$3,000,000 each claim limit, a \$6,000,000 aggregate limit, and a \$5,000 each claim deductible.
- 9. The policy provides medical professional liability coverage on a claims-made basis, and contains the following relevant provisions:

Part I. Insuring Agreements

A. Covered Services

The Company will pay on behalf of the Insured, as shown in the Declarations, all sums that the Insured becomes legally obligated to pay as Damages and associated Claim Expenses arising out of a negligent act, error or omission, even if such Claim is groundless, false or fraudulent, in the render ng of or failure to render professional services as described in the Declarations, provided that the:

- Claim is first made against the Insured during the Policy Period, and reported to the Company no later than thirty (30) days after the end of the Policy Period;
- Negligent act, error or omission took place in a covered territory;
- Negligent act, error or omission took place after the Retroactive Date as shown in the Declarations.

C. Policy Limits

Regardless of the number of persons or entities insured or included in Part I. E. Covered Persons and Entities, or the number of claims made against the Insured:

- The maximum liability of the Company for Damages and Claim
 Expenses resulting from each Claim first made against the Insured
 during the Policy Period and the Extended Reporting Period, if
 purchased, shall not exceed the amount shown in the Declarations as
 each Claim;
- The maximum liability of the Company for all Damages and Claim Expenses as a result of all Claims first made against the Insured during the Policy Period and the Extended Reporting Period, if Lurchased, shall not exceed the amount shown in the Declarations as Aggregate.

The Company shall not be obligated to pay any Claim for Damages or defend any Claim after the applicable Limit of Liability has been exhausted by payment of judgments, settlements, Claim Expenses or any combination thereof. Claim Expenses are part of and not in addition to the applicable Limits of Liability. Payment of Claim Expenses by the Company reduces the applicable Limits of Liability.

The inclusion of more than one Insured, or the making of Claims by more than one person or organization, does not increase the Company's Limit of Liability. In the event two or more Claims arise out of a single negligent act, error or omission, or a series of related negligent acts, errors or omissions, all such Claims shall be treated as a single Claim. Whenever made, all such Claims shall be considered first made and reported to the Company during the Policy Period in which the earliest Claim arising out of such negligent act error or omission was first made and reported to the Company, and all such Claims shall be subject to the same Limit of Liability,

Part III. Definitions

* * *

- Claim means a written or verbal demand, including any incident, occur ence or offense which may reasonably be expected to result in a claim, received by the Insured for money or services, including service of suit or institution of arbitration proceeding against the Insured.
- Landmark is currently defending ARL in the underlying lawsuits under a reservation of rights.

IV.

REQUEST FOR DECLARATORY RELIEF

- 11. The claims for injuries associated with use of the steroid asserted against ARL arise out of a series of related negligent acts, errors, or ommisions—the alleged negligent testing of the steroid samples provided by NECP. Thus, under the Landmark policy's language, the claims are treated as a single claim and the \$3,000,000 per claim limit applies.
- 12. Accordingly, Landmark seeks a declaration from this Court that only the \$3,000,000 per claim limit, and not the \$6,000,000 aggregate limit applies to satisfy all claims or suits asserted against ARL arising from the underlying event.

V.

PRAYER

- 13. Wherefore, premises considered, Landmark requests that the Court issue an Order:
 - a. finding that the claims asserted in the underlying lawsuits, and all other claims asserted against ARL for injuries, arise out of a series of related, allegedly negligent acts, errors, or omissions and are therefore treated as a single claim; and,
 - b. holding that because they are treated as a single claim, \$3,000,000 per claim limit, and not the \$6,000,000 aggregate limit applies to satisfy all claims or suits asserted against ARL arising from the underlying event; and,
 - c. granting any and all further relief this Court deems just and to which Plaintiffs are entitled.

Respectfully Submitted,

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PLAN PROPONENTS' EXHIBIT 5

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UNITED STATES BANKRUPTCY COURT DISTRICT OF MASSACHUSETTS EASTERN DIVISION

In re:)	
)	Chapter 11
NEW ENGLAND COMPOUNDING)	
PHARMACY, INC.,)	Case No. 12-19882-HJB
)	
Debtor.	<u> </u>	

<u>DECLARATION OF PATRICK T. FENNELL IN SUPPORT OF CONFIRMATION OF FIRST AMENDED JOINT CHAPTER 11 PLAN OR NEW ENGLAND COMPOUNDING PHARMACY, INC. AND FOR APPROVAL OF INSIGHT SETTLEMENT</u>

- 1. I, Patrick T. Fennell, declare under penalty of perjury on the date identified below, as follows:
- 2. I am an attorney at the law firm Crandall & Katt, in Roanoke, Virginia. I have been practicing personal injury and products liability law for over 18 years, and I am lead counsel in Crandall & Katt's mass tort practice group.
- 3. I am a member of the Plaintiffs' Steering Committee appointed by the Hon. F. Dennis Saylor, IV, then-presiding Judge in the matter *In re:*, *New England Compounding Pharmacy, Inc. Products Liability Litigation*, MDL No. 1:13-md-2419, pending in the United States District Court for the District of Massachusetts ("MDL").
- 4. I also represent 68 individual personal injury and wrongful death claimants in this bankruptcy proceeding.² As such, I am one of nine (9) attorneys ("Virginia plaintiffs' counsel") representing all of the 153 represented claimants in the MDL and in this bankruptcy proceeding who have claims against both the debtor and the "Virginia Defendants", arising from the injection into claimants' bodies (or the bodies of their decedents) of contaminated MPA compounded and distributed by the debtor (the "represented Virginia claimants").⁴ Among the Virginia claims are eight wrongful death claims.
- 5. On December 27, 2012, Sharon G. Wingate, Executor of the Estate of Douglas Gray Wingate, deceased, filed her complaint against the Virginia defendants for the wrongful death of her husband, in the Circuit Court for the City of Roanoke, in Roanoke, Virginia (Case No. CL12-2547). Mrs. Wingate alleged, in part, that her husband died from an infection caused

¹ MDL Doc. 82.

² Sixty-three of whom also have claims against Virginia defendants.

³ The "Virginia Defendants" are Insight Health Corp. ("Insight"), Image Guided Pain Management, P.C. ("IGPM"), John M. Mathis, M.D. ("Dr. Mathis") and Robert F. O'Brien, M.D. ("Dr. O'Brien").

⁴ There are an estimated 64 additional claimants not currently represented by counsel, who may also have claims against the debtor and/or Virginia defendants.

by the injection into his body of contaminated MPA compounded and distributed by the debtor. The injection was performed at a facility owned and operated by Insight in Roanoke, Virginia.

- 6. Wingate was pending in Roanoke City Circuit Court when, in February, 2014, a settlement agreement was reached between the plaintiff and Virginia defendant Insight, pursuant to which Insight agreed to pay \$4.5 million to Mr. Wingate's estate.
- 7. Although the merits of the remaining cases against Insight and Dr.'s Mathis and O'Brien were substantially developed in the *Wingate* case, the settlement of *Wingate* also depleted the insurance coverage available to satisfy the remaining Virginia claims, including an additional seven claims for wrongful death, by the significant amount of \$4.5 million...
- 8. Subsequently, from August, 2014 through February, 2015, Virginia plaintiffs' counsel conducted a prolonged mediation with counsel for the Virginia defendants (the "Virginia mediation"). The Virginia mediation included approximately eight full days of "in-person" mediation sessions with two mediators, and one settlement conference in the MDL Court with the direct involvement of the Hon. Rya W. Zobel, presiding Judge, and the Hon. Jennifer C. Boal, Magistrate Judge.
- 9. I personally participated in all mediation sessions and the settlement conference, as well as many hours of negotiations by telephone and other means of communication over approximately six months. Additional participants in the Virginia mediation and negotiations included the Chapter 11 Trustee, Paul D. Moore (alternately in person and/or by counsel), Lead Counsel in the MDL, representatives of the Plaintiffs' Steering Committee (in addition to me), and representatives of the Official Committee of Unsecured Creditors.
- 10. While participating in the mediation efforts, I and the other Virginia plaintiffs' counsel concluded that uncoordinated, one-off resolutions of the Virginia cases (as in *Wingate*, for example), would not only create a chaotic rush to the courthouse and further deplete available insurance coverage in a haphazard fashion, but would likely leave many Virginia plaintiffs with no source of recovery from Insight and IGPM. We further concluded that a global resolution was preferable because it would preserve assets for all litigants, create the opportunity for distribution of assets in an organized and equitable fashion, and allow Insight the opportunity to consider contribution of amounts in excess of the available insurance coverage.
- Agreement between the represented Virginia claimants and Virginia defendants, pursuant to which the Virginia defendants will pay \$40 million for the benefit of the Virginia claimants (the "Insight Settlement Agreement"). The \$40 million sum consists, in part, of a contribution by Insight alone of \$38.5 million, which is \$7 million in excess of its stated available insurance coverage. On information and belief, each and every of the 153 individual represented Virginia claimants has signed the Insight Settlement Agreement.

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⁵ See Doc. 1123, Notice of Filing of Plan Supplement Re: Chapter 11 Plan of Reorganization of New England Compounding Pharmacy, Inc., Exhibit 5.

- 12. The depletion of insurance coverage available to resolve the remaining Virginia claims, resulting from the *Wingate* settlement, was a significant factor in the decision of Virginia counsel to recommend to their clients a settlement with the Virginia defendants involving payment of a total of \$40 million.
- 13. In my opinion, under the foregoing circumstances, along with other facts and circumstances that I anticipate will be presented to the Court, the Insight Settlement Agreement is a fair, reasonable and equitable outcome for the Virginia claimants. Alternatives to this settlement would necessarily mean piecemeal litigation drawn out over many years, an uncertain outcome, and less (potentially much less) money available to satisfy judgments, for a group of plaintiffs many of whom are elderly and need the money this settlement will provide sooner rather than later. I therefore strongly support confirmation of the First Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. and approval of the Insight Settlement Agreement.

Executed on this 27th day of April, 2015, in Roanoke, Virginia.

Patrick T. Fennell (VSB 40393)

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PLAN PROPONENTS' EXHIBIT 6

UNITED STATES BANKRUPTCY COURT DISTRICT OF MASSACHUSETTS EASTERN DIVISION

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NEW ENGLAND COMPOUNDING PHARMACY, INC.,

Debtor.

Chapter 11

Case No. 12-19882-HJB

DECLARATION OF J. SCOTT SEXTON IN SUPPORT OF CONFIRMATION OF FIRST AMENDED JOINT CHAPTER 11 PLAN OF NEW ENGLAND COMPOUNDING PHARMACY, INC. (RELATING TO SETTLEMENT WITH INSIGHT HEALTH CORP., AND OTHERS – VIRGINIA)

A. Introduction and Description of the Participation of Virginia Plaintiffs:

- 1. My name is J. Scott Sexton. I have personal knowledge of all matters set forth in this Declaration, except for those matters stated to be upon information and belief, and I believe all such matters to be true and correct. I am competent to testify under oath to the matters set forth in the Declaration if called to do so. I submit this Declaration in support of confirmation of the Joint Chapter 11 Plan of the New England Compounding Pharmacy, Inc. [Docket No. 1054] (as amended at Docket No. 1154 and thereafter, from time to time, and including all exhibits and supplements thereto, the "Plan") and, more specifically, as it relates to the settlement of claims against Insight Health Corp. ("Insight") and associated physicians, Dr. John Mathis and Dr. Robert O'Brien and their practice group, Image Guided Pain Management (collectively "IGPM") relating to injections of NECC MPA provided in Roanoke, Virginia.
- 2. I am an experienced trial attorney in good standing in Virginia. Since 1988, I have practiced with the Gentry Locke law firm in Virginia.
- 3. Beginning in October of 2012, our firm has represented 16 seriously injured individuals and 3 decedents' estates for personal injury and wrongful death claims arising from injections of contaminated methylprednisolone acetate ("MPA) compounded by New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC"), at the Insight clinic in Roanoke, Virginia.
- 4. Our representation of these plaintiffs focused primarily on the liability of Insight and IGPM. After NECC filed for bankruptcy protection, we aggressively filed and pursued state law claims against Insight and IGPM in the Circuit Court for Roanoke City, Virginia. The wrongful death case of *Wingate v. Insight Health Corp.*, was the first case that was worked up

for trial. In the course of preparing this case, we obtained thousands of pages of documents from the defendant, conducted 19 depositions, and obtained detailed expert reports. A trial date for the *Wingate case* was set to start on April 21, 2014, in the Roanoke City Circuit Court in Virginia.

- 5. The *Wingate* case was resolved by agreement in late January 2014, and the settlement was later approved by the Circuit Court.
- 6. While the *Wingate* case was pending, the Judicial Panel for Multidistrict Litigation entered an order designating the U.S. District Court for Massachusetts as the MDL Court for all claims against NECC and other related third-parties entitled *In re New England Compounding Pharmacy, Inc. Product Liability Litigation*, MDL Docket No. 2419, Master File No. 1:13-MD-02419-RWZ ("MDL Court").
- Before the *Wingate* case was resolved, the Chapter 11 Trustee for the NECC Bankruptcy ("NECC Trustee") filed a motion with the MDL Court to enter an order that would remove all of the cases against Insight and IGPM which were then pending in Virginia state court arising out of the NECC MPA injections to federal court and transfer them to the MDL Court. In June, 2014, the MDL Court entered the requested Order. Cases that were subsequently filed were transferred or removed to the MDL based upon this ruling. Ultimately, all the 153 claims of former patients who had sued Insight and IGPM in Virginia state courts as a result of injuries and deaths caused by having received one or more injections of NECC MPA administered by IGPM at Insight's Roanoke clinic (the "Virginia Plaintiffs") (this number includes the remaining 18 plaintiffs represented by our firm), were transferred to the MDL Court in Boston. The Virginia Plaintiffs are represented by nine law firms.
- 8. On August 22, 2014, the Virginia Plaintiffs agreed to submit their claims against Insight and IGPM to a mediation that involved Insight, IGPM, the NECC Trustee, Official Unsecured Creditors Committee from the NECC Bankruptcy, and the Plaintiffs Steering Committee from MDL 2419. This mediation did not involve or include separate claims the Virginia Plaintiffs have made against NECC in the Bankruptcy Court by virtue of having filed Proofs of Claims.
- 9. The Virginia Plaintiffs represent <u>all</u> of the 153 persons or their estates known to have filed a claim against Insight and/or IGPM arising out of injections of NECC MPA at the Roanoke, Virginia clinic (which is the only clinic at which Insight injected the NECC MPA).
- 10. As a result of the extensive discovery and expert witness development conducted in the lead *Wingate* case, the Virginia Plaintiffs entered the mediation with a fully-developed factual record and with confidence in the underlying legal merits of their claims. Additionally, the law firms representing the Virginia Plaintiffs gathered, and with the clients' consent, shared detailed information regarding the types of injuries suffered and the expenses incurred by each plaintiff. Thus, counsel for the Virginia Plaintiffs not only had detailed knowledge regarding the alleged liability of the defendants, but also the injuries that the 153 plaintiffs had sustained.

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- 11. Among the 153 cases there are eight death cases, and the majority of the remaining 145 surviving Virginia Plaintiffs are elderly. This demographic factor along with circumstances related to each plaintiff, caused the Virginia Plaintiffs to strongly encourage their counsel to seek an agreed settlement if a fair resolution could be achieved.
- 12. In connection with and prior to the start of the mediation, Insight provided confidential financial statements to counsel for the Virginia Plaintiffs in order provide the Virginia Plaintiffs with a factual basis on which to determine Insight's ability (if any) to fund a settlement beyond its available insurance coverage.
- 13. The mediation of these claims formally began on September 11, 2014, when the Virginia Plaintiffs presented the merits of their cases to the two mediators selected by the parties. These detailed presentations on liability and damages to the mediators provided a solid basis for the ultimate success of the mediation. At the end of the formal presentations, all 153 plaintiffs were invited to attend a meeting with the mediators in a hotel ballroom, which was well attended. This process included a vigorous question and answer session.
- 14. The mediation process took place over nearly six (6) months, covering the period August 22, 2014 to February 12, 2015. There were multiple face-to-face sessions including five days in Roanoke, one day in Northern Virginia, and 3 days in Boston. At each significant step of the mediation, we provided detailed information to our clients regarding the issues and obstacles. On information and belief, the other counsel representing the Virginia Plaintiffs did the same with regard to their respective clients.
- 15. Ultimately, each and every one of the 153 Virginia Plaintiffs overwhelmingly supported the settlement that was achieved and unanimously voted to accept the Settlement Agreement with Insight and IGPM that is reflected in the Plan; and each of the 153 Virginia Plaintiffs signed the Settlement Agreement.

B. <u>Insight, IGPM, their Insurers, their respective disputes, and the key terms of the settlement:</u>

- 16. Insight is a Delaware corporation with a principal place of business in Minneapolis, Minnesota. Insight purchased the clinic at issue in Roanoke, Virginia in 2010. At that time, the Roanoke clinic was already using MPA from NECC.
- 17. In connection with the purchase of the Roanoke clinic, Insight entered into a contractual agreement with the local physicians, Dr. John Mathis and Dr. Robert O'Brien, who were already practicing at the Roanoke clinic. Those doctors continued to work at the Insight clinic through their practice group, Image Guided Pain Management ("IGPM").
- 18. Lexington Insurance Company ("Lexington") issued two liability policies to Insight that provided coverage for claims made by the Virginia Plaintiffs. Insight also maintained an excess or umbrella policy with Darwin Select Insurance Company ("Darwin") that provided secondary coverage for these claims.

- 19. Based upon the resolution of state court litigation before the claims of the 153 Virginia Plaintiffs were transferred to the MDL, the remaining uncontested insurance coverage between the Lexington and Darwin policies totaled \$31.5 million for purposes of the mediation.
- 20. IGPM's insurance coverage proved to be challenging. IGPM and its member doctors (also defendants) held a policy issued by Medical Mutual of North Carolina ("Medical Mutual"). In response to the lawsuits filed by the Virginia Plaintiffs, Medical Mutual defended under a reservation of rights and filed a federal lawsuit challenging its duty to defend IGPM and the doctors, as well as it coverage of the claims. After losing on its request for declaratory judgment that it had no duty to defend the claims, Medical Mutual appealed the district court decision to the U.S Court of Appeals for the Fourth Circuit, where the case remained as of the date of settlement. Medical Mutual never relented in its aggressive position on a lack of coverage, and this proved to be a major challenge in the efforts to settle the claims.
- 21. The amount of coverage for IGPM was also a disputed issue. Responses to discovery by IGPM revealed \$6 million in total combined coverage for the practice group and the two doctors. However, a theory developed during the course of the mediation that the Medical Mutual policy could be read to provide \$6 million per insured (which meant that the policy could provide a potential total of \$18 million in coverage, assuming that the plaintiffs prevailed against each of the three insureds).
- Another significant complication to settlement was the fact that Insight and IGPM had asserted cross claims against each other based on contractual indemnity in all of the cases filed by the Virginia Plaintiffs. Insight had contracted to provide management services to the practice, and IGPM had contracted to provide professional services to patients at the Roanoke clinic. Each claimed that if liability were to be found against them, then the other should be responsible based upon their contractual obligations. As the negotiations progressed it became clear that no settlement with Insight could be reached without including IGPM and the doctors because the joint tortfeasor settlement statute in Virginia could only extinguish claims for contribution and not for indemnity. Insight refused to settle without simultaneous resolution of its potential risk for indemnity claims by IGPM. This risk could only be eliminated by a joint settlement with mutual releases between Insight and IGPM.
- 23. Given these complications, Judge Zobel ordered the decision-makers for the parties and their counsel her courtroom in Boston with the express purpose of expediting a conclusion to the mediation. This mediation occurred on December 18, 2014, with Judge Zobel and Magistrate Judge Boal actively participating in the mediation meetings with parties. Notwithstanding the direct efforts of Judge Zobel, the parties remained unable to resolve significant details, including reaching a "global settlement" with both Insight and IGPM.
- 24. The nine firms representing the Virginia Plaintiffs are all experienced trial attorneys in Virginia who have substantial experience in handling complicated personal injury and medical practice claims. Despite the lack of success of the court-facilitated Boston mediation on December 18, 2014, with assistance from the NECC Trustee, the Creditors' Committee, and Plaintiffs Steering Committee, counsel for the Virginia Plaintiffs persuaded the mediators to continue work to overcome the obstacles to settlement.

25. Through continued work in January and February 2015, and an agreement among the NECC Trustee, Plaintiffs Steering Committee and the Virginia Plaintiffs, the parties ultimately reached agreement effective February 12, 2015 on the elusive global settlement, with Insight and IGPM agreeing to mutual releases of each other as a condition of settlement. All mediators, the counsel for the Virginia Plaintiffs, the NECC Trustee, the Official Unsecured Creditors Committee, and the Plaintiffs' Steering Committee endorsed the terms of the settlement as a great achievement for the injured parties.

C. The key terms of the settlement:

As noted in the Plan, under the Settlement Agreement, the defendants and their insurers agreed to pay a total of \$40 million, including a substantial contribution by Insight above and beyond its available insurance coverage. The \$40 million has been deposited into an interim escrow account, and is subject to refund only as provided in the Settlement Agreement, including but not limited to the failure to confirm the chapter 11 plan with the plan releases and injunction. Nearly 90% of this settlement amount is payable upon the Plan Effective Date, with the remainder being held back in escrow in the event of an appeal of an order confirming the Plan. This allows prompt payment to the NECC Estate and the injured parties, regardless of appeals that might be filed. The parties to the settlement believe that ultimately all of the holdback funds will go to the benefit of the NECC Estate and the injured parties, subject only to payments that might be required to satisfy a small subset of theoretically possible claims against Insight that have not and are not practically expected to be filed.

D. The reasonableness of the Insight Settlement:

- 27. In my opinion, there is no doubt that the settlement reached on the claims against Insight and IGPM is an exceptional result and is a very reasonable outcome for our clients and all of the Virginia Plaintiffs given a number of factors, including the following:
 - a) Delay and expense associated with litigating 153 cases: Without doubt the trial of these cases would have been extraordinarily expensive and there was likely to be substantial delay in getting these cases ready to be tried against these defendants. While an effort to consolidate the cases for a trial on liability was a possibility, the outcome of such a motion was an uncertain, and even if granted would have been a difficult undertaking, and would not have solved the practical problems associated with trying and proving damages associated with so many claims. With 8 death cases and another 40-50 very serious injury claims, there was a legitimate concern that the range of potential recoveries was well above the insurance coverage available even if all coverage issues were resolved in favor of the plaintiffs (and insureds). The expenses of litigation and the delay of an extended trial schedule were thus factored into this ultimate potential recovery (assuming all wins and all coverage), and the small incremental potential gains were not sufficient to offset the extraordinary associated expense of trial(s), even without factoring in the risk of defense rulings and the potential for loss on the coverage disputes (addressed below).

- b) <u>Contested liability</u>: Both Insight and IGPM contested liability and promised to present a vigorous defense. Insight had developed a number of nationally-recognized experts to bolster its defense, and either or both might have convinced juries that the true fault rested with NECC, which produced the contaminated steroids without their knowledge, and through possible criminal acts.
- c) <u>Insurance coverage disputes</u>: IGPM's insurance carrier was unrelenting in its challenge to any coverage, and was vigorously pursuing litigation to that end. During the six months of negotiations, no progress was made in gaining any concession from Medical Mutual on the extent of its coverage obligation.
- d) Limited resources (collectability and more delay): IGPM had no known assets of significance apart from its insurance coverage. The information provided by Insight provided no objective basis for the Virginia Plaintiffs, the Trustee, the Creditor's Committee or the PSC to believe that a substantial verdict in excess of insurance coverage could be collected. There was also substantial concern that Insight might file for bankruptcy protection, especially if one of the first cases tried resulted in a substantial verdict. Since Insight had been purchased out of bankruptcy in 2010 by the current owner, there was heightened concern that the owner's familiarity with the reorganization process might make it more willing to seek this protection. Counsel for the Virginia Plaintiffs were concerned that a successful series of trials against Insight would likely only open a new chapter of bankruptcy, further delaying recovery to the injured parties and depleting the recovery of the injured parties through administrative expenses.
- e) <u>Injured party demographics and desires</u>: The majority of the parties asserting claims against Insight and IGPM are elderly and many are in poor health. They expressed an overwhelming desire to resolve the cases as quickly as possible by settlement. Many of our more elderly clients expressed a desire to bring closure to this dispute rather than passing it on to their heirs and estates as an additional burden to pursue on their behalf. Ultimately, <u>all</u> of the injured parties who had asserted claims against Insight and IGPM agreed to the settlement and signed the settlement agreement.
- f) Potential decline in "value" of numerous cases: It is an unpleasant reality that the monetary "value" of a substantial personal injury claim will often decline when the plaintiff dies. This is particularly true when the plaintiff is elderly and death is not caused by the underlying personal injuries that lead to the claim. Given the demographics of the Virginia Plaintiffs, counsel for these parties recognized the substantial likelihood that a number of the Virginia Plaintiffs would die prior to any trial date. As a result, delay (by default) favored the defense in almost all cases and particularly in cases where the plaintiff was ill and might die before the trial date. This fact was not lost on these defendants. Thus, the value of many of the cases used in the mediation to establish significant damage exposure might have declined with

¹ By this I mean only the likely range of jury verdict, not the measure of real harm experienced by the injured party.

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the passage of time over the next several years. Thus, these defendants had every incentive to prolong and delay the ultimate trial of these cases for as long as possible.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Dated: April 28, 2015

By:

J Scott Sexton (VSB No. 29284)

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PLAN PROPONENTS' EXHIBIT 7

UNITED STATES BANKRUPTCY COURT DISTRICT OF MASSACHUSETTS EASTERN DIVISION

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NEW ENGLAND COMPOUNDING PHARMACY, INC.,

Chapter 11

Case No. 12-19882-HJB

Debtor.

DECLARATION OF THOMAS M. SOBOL IN SUPPORT OF APPROVAL OF THE UNIFIRST SETTLEMENT AND IN SUPPORT OF APPROVAL OF THE FIRST AMENDED JOINT CHAPTER 11 PLAN OF NEW ENGLAND COMPOUNDING PHARMACY, INC.

- I, THOMAS M. SOBOL, declare and state as follows:
- 1. I am a partner with the law firm Hagens Berman Sobol Shapiro LLP and member of the bar of the Supreme Judicial Court of the Commonwealth of Massachusetts. I have been practicing law for over 30 years and have been admitted *pro hac vice* in numerous jurisdictions and district courts across the country. I make this declaration in support of the proposed settlement with the UniFirst Corporation as incorporated into the First Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. (the "Plan").
- 2. Unless otherwise stated, I have personal knowledge of the matters stated herein and, if called upon, I would competently testify thereto. I attest to all other matters upon information and belief, based on investigation conducted by myself, members of my firm or members of the PSC.

MY BACKGROUND

3. I have been the managing partner of the Boston office of Hagens Berman Sobol Shapiro LLP ("HBSS") for fourteen years, and before that a partner in the Boston office of Leif Cabrasser Heiman and Bernstein for two years, where I represented plaintiffs exclusively. I

spent the previous seventeen years with the Boston-based law firm of Brown Rudnick LLP, representing large and small institutions, partnerships, and individual persons in complex criminal and civil matters.

- 4. I have significant bankruptcy and financial institution experience. As a plaintiffs' litigation attorney, I have handled matters against large institutions in both distressed and non-distressed situations. I have also defended large and small debtors and creditors. I have tried cases in bankruptcy and financial matters while a partner at Brown Rudnick LLP. I also worked in conjunction with the creditors' committee in the W.R. Grace Bankruptcy for Zonolite asbestos claims.¹
- 5. I have written an article addressing the practical aspects and benefits of limited fund classes in situations where the defendant does not have adequate assets to fully compensate all tort claimants.²
- 6. My firm specializes in the representation of plaintiffs in class actions and multiparty, large-scale complex litigation and is regularly listed in the National Law Journal's Plaintiffs' Hot 100 List. I personally have significant experience representing plaintiffs in complex pharmaceutical class actions.

COURT-APPOINTED POSITIONS

7. I am Court-appointed Lead Counsel and a member of the seven person Plaintiffs' Steering Committee ("PSC") in this associated MDL, *In re New England Compounding Pharmacy, Inc. Products Liability Litigation*, 1:13-md-2419-RWZ (D. Mass.) (the "MDL") pending before the Honorable Rya W. Zobel (the "MDL Court"). As Lead Counsel, I have been

¹ In re W.R. Grace, 01-cv-1139 (Bankr. D. Del. 2001).

² Elizabeth J. Cabraser and Thomas M. Sobol, *Equity for the Victims, Equity for the Transgressor: The Classwide Treatment of Punitive Damages Claims*, 74 Tul. L. Rev. 2005.

charged by the MDL Court with comprehensively coordinating pretrial strategy, discovery, mediation, and authorizing settlement of claims on behalf of all tort victims in the MDL.³

- 8. I serve as a member of the Official Committee of Unsecured Creditors ("OCC"), through a proxy from my client Mr. Robert Cole.⁴
- 9. I have been involved in this litigation from its inception in the fall of 2012. Very early in the proceedings and before the MDL was formed, I sought and obtained pre-judgement attachment of the tangible assets of NECC.⁵ My firm also participated in and helped to coordinate the early inspection of the NECC facility in December 2012.

EARLY LITIGATION AGAINST UNIFIRST

- 10. UniFirst Corporation ("UniFirst") is a Massachusetts corporation with its principal place of business at 68 Jonspin Road, Wilmington, Massachusetts. UniFirst contracted with NECC to provide cleaning services that included the cleaning of the "cleanrooms" used to manufacture and/or compound drugs, including the NECC drugs responsible for this tragedy. UniFirst's corporate mission is to be recognized as the "quality leader" in the cleaning and garment industry and, upon information and belief, it represents to its customers that hiring UniFirst will "improve the safety and cleanliness" of their business facility.
- 11. Among other cleaning duties, NECC paid UniFirst to mop and sanitize the floors, walls and ceilings of each NECC cleanroom, and each pass-through leading to each cleanroom, on a monthly basis. UniFirst was responsible for vacuuming all floors with a HEPA filtered vacuum system. The company's workers were then required to first clean pass-through areas, including walls and ceilings, and then separately sanitize them with isopropyl alcohol. The

³ Order Appointing Lead Counsel and Plaintiffs' Steering Committee, MDL Dkt. 82.

⁴ Dkt. 67.

⁵ Erkan Dkt. 38, 12-cv-12052.

⁶ UniFirst may also do business as UniClean Cleanroom Services ("UniClean"), and shall be referred to herein as "UniFirst." UniClean is a division of UniFirst.

company was supposed to mop all floors, and then sanitize all floors using UniFirst's proprietary cleanroom mopping systems with materials provided by UniFirst. UniFirst was also responsible for cleaning and sanitizing all exterior hoods in each NECC cleanroom. In accordance with its contractual obligations and industry standards for good cleanroom procedures the two-step process of cleaning and then sanitizing was mandatory for each task.

- 12. Industry standards require that each action take due time, diligence, and attention to detail, since many particles and contaminants are not visible to the human eye. UniFirst was required to perform these services at NECC and use these products on a monthly basis for two years prior to the outbreak in the fall of 2012.
- 13. The Master Complaint filed on November 5, 2013⁷ named UniFirst as a defendant. The Master Complaint states:

Defendant UniFirst Corporation ("UniFirst") was hired by NECC to clean the NECC and Ameridose clean rooms, including the clean rooms where the contaminated products were manufactured. . . . NECC's internal records report numerous instances of reported mold and bacterial contamination in the months leading up to the outbreak. UniFirst failed to provide adequate cleaning services that would have prevented contamination of the drugs made in those clean rooms."

14. UniFirst's negligence was reasonably clear even at the pre-discovery stage.

Conditions leading to fungal and other contamination were rife at the NECC facilities during

2012. UniFirst was the only outside, industrial cleaner responsible for assuring industrial

sanitary conditions for a pharmacy compounding "clean room" facility. Upon information and
belief, UniFirst repeatedly departed from both industry standards and contractual requirements,
not only failing to accomplish rudimentary clean health standards, but at times exacerbating the
unsanitary conditions at NECC.

⁷ Amended Master Complaint, MDL Dkt. 545.

15. I believe that UniFirst failed to undertake its duties in accordance with industry and contractual standards. However, as UniFirst only visited NECC one time a month, I also recognize that it may be difficult to prove that UniFirst's negligence was a substantial contributing factor that caused the contamination of the three compounded batches of methylprednisolone acetate ("MPA") from the NECC cleanrooms.

MEDIATION EFFORTS

A. Demand letter and mediation briefs.

- 16. I and other members of the PSC, along with the Chapter 11 Trustee, the OCC, and UniFirst began discussing the possibility of resolving claims against UniFirst through mediation in early 2014.
- 17. On May 15, 2014, the PSC served UniFirst with a comprehensive demand that set out the substantive basis for plaintiffs' claims against UniFirst. The PSC's demand consisted of 40 pages and dozens of exhibits detailing UniFirst's failure to meet industry standards related to proper clean-room cleaning and sanitization procedures, as well as their own standard operating procedures and those of NECC.
- 18. In June and July of 2014, the PSC and UniFirst, with involvement of the Trustee and the OCC, agreed to mediate privately, outside of the court-ordered mediation program, with David Geronemus of JAMS Arbitration, Mediation, and ADR Services. The parties exchanged mediation briefs in late summer and early fall of 2014.

B. October 17, 2014 Mediation

19. Due to scheduling conflicts, the first in-person mediation did not take place until October 17, 2014. The PSC, counsel for and representatives of the OCC, and the Trustee attended the mediation for the MDL plaintiffs and bankruptcy creditors. UniFirst's MDL counsel and insurers attended for UniFirst.

- 20. The mediation occurred in the context of attempting to resolve UniFirst's claims for indemnification against the debtor in addition to resolving the tort victim's claims against UniFirst. Despite a day-long effort by all parties and some limited progress, no resolution was reached, although the parties' positions at that time showed the obvious middle point at which an agreement might be reached.
 - 21. During the October in-person mediation, the following issues were in dispute:
 - a. Whether UniFirst was responsible for sanitizing the floors, walls, and pass-throughs pursuant to its contract with NECC;
 - b. Whether certain independent cleaning and sanitizing pharmaceutical compounding guidelines applied to cleaning companies like UniFirst;
 - c. Whether UniFirst was required to use sporicidal cleaners on the cleanroom surfaces;
 - d. Whether NECC could have reasonably expected UniFirst to adequately sanitize the cleanroom when UniFirst only visited the NECC facility for 90-120 minutes a month;
 - e. Whether there were ongoing problems with the gowning procedures employed by UniFirst;
 - f. Whether UniFirst's own written standard operating procedures for the sanitization of pharmaceutical cleanrooms applied to work done in the NECC cleanrooms;
 - g. Whether NECC provided UniFirst with NECC's own internal cleanroom standard operating procedures; and
 - h. Whether there was a correlation between UniFirst's visits and bacterial and/or fungal contamination in the NECC cleanrooms.

C. Further mediation efforts

- 22. Following the October in-person mediation session, the parties continued discussing a possible resolution of claims against UniFirst. On December 3, 2014, the date the Plan was originally filed, the parties had not yet reached an agreement in principle. The parties continued through discussions with the mediator, both separately and together, to seek resolution (*i.e.*, basically the parties inched toward that mid-point).
- 23. On February 22, 2015, the parties signed a settlement agreement. UniFirst agreed to contribute \$30.5 million to the NECC bankruptcy estate in exchange for, among other things, a non-debtor release.
- 24. On February 23, 2015, the Trustee filed the Plan Supplement, which incorporated the UniFirst Settlement.

REASONABLENESS OF THE SETTLEMENT

- 25. I believe that the proposed settlement with UniFirst is fair and reasonable and in the best interest of all tort victims in the MDL for the following reasons:
 - A. Establishing liability against UniFirst at trial would be difficult, costly, and take years of continued litigation.
- 26. The PSC was prepared to litigate against Unifirst, but the outcome of such efforts was far from certain. Overcoming UniFirst's asserted defenses, particularly as they relate to the issue of causation, would be an uphill battle and require a tremendous expenditure of resources over a long period of time.
- 27. UniFirst vigorously maintained that it bore no responsibility for the outbreak (see *supra* para 21). While the PSC had a basis for contesting UniFirst's defenses, there were serious questions about the ability to prove that UniFirst directly caused the fungal contamination in the batches of MPA.

- 28. Establishing liability and damages as to UniFirst was further hampered by UniFirst's document retention policies, the questionable record keeping at NECC, and an anticipated lack of deposition testimony from the NECC insiders. While none of these should permit UniFirst to escape liability, all had the practical effect of making the case against UniFirst harder to prove.
- 29. Given my extensive litigation experience with such matters, I harbored serious concerns that Plaintiffs would be able to recover significantly more than \$30.5 million in the aggregate for tort victims within a reasonable period of time through multiple, individual trials.
 - B. The settlement with UniFirst represents a substantial contribution to the bankruptcy estate.
- 30. UniFirst's \$30.5 million contribution is the largest contribution from a national defendant. For comparison, the other national defendants, ARL and Victory, contributed \$6.4 million and \$4.5 million respectively.
 - C. The proposed Plan and non-debtor releases provided an incentive to UniFirst to settle.
- 31. The approach chosen long ago for resolving the NECC catastrophe non-debtor releases in exchange for significant contributions to the bankruptcy estate provided a vehicle for the resolution of creditors' claims against UniFirst that would not have otherwise been available in a non-bankruptcy context. From the early stages of litigation UniFirst stated that it was only interested in settling if it could resolve all tort victims' claims against it. Without the settlement, significant compensation from UniFirst to the victims of this tragedy would be in doubt. Without the settlement, if financial compensation from UniFirst for the victims ever came, it would only be after years of continued litigation and a significant delay in justice for the victims of this tragedy.

CONCLUSION

32. It is my belief the settlement with UniFirst as incorporated in the proposed Plan is fair, reasonable, and serves the best interests of tort victims in the MDL.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Dated: April 27, 2015

Respectfully submitted,

Thomas M. Sobol

Lead Counsel for Plaintiffs' Steering Committee in MDL 2419

PLAN PROPONENTS' EXHIBIT 8

UNITED STATES BANKRUPTCY COURT DISTRICT OF MASSACHUSETTS EASTERN DIVISION

In re:	
NEW ENGLAND COMPOUNDING PHARMACY, INC.,	Chapter 11 Case No. 12-19882-HJB
Debtor.	

DECLARATION OF MATTHEW K. DOONAN, ESQ. IN SUPPORT OF CONFIRMATION OF FIRST AMENDED JOINT CHAPTER 11 PLAN OF NEW ENGLAND COMPOUNDING PHARMACY, INC.

- I, Matthew K. Doonan, Esq., submit this declaration in support of confirmation of the Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. [Docket No. 1054] (as amended at Docket No. 1154 and thereafter from time to time, and including all exhibits and supplements thereto, the "Plan"), and respectfully state as follows:
 - 1. I am the General Counsel of Inspira Health Network, Inc.
- 2. Inspira Health Network, Inc. is incorporated in the State of New Jersey as a non-profit, non-stock, 501(c)(3) charitable organization. Inspira Medical Centers, Inc. is also incorporated in the State of New Jersey as a non-profit, non-stock, membership, 501(c)(3) charitable organization. Inspira Health Network, Inc. is the sole member of Inspira Medical Centers, Inc. (collectively, "Inspira").
 - 3. I am authorized on make this declaration on Inspira's behalf.
- 4. Inspira purchased methylprednisolone acetate ("MPA") produced by New England Compounding Pharmacy, Inc. ("NECC").

Cases 42-1-18882 - Data 232/67 Bill 4 10-10 285 115-7 Enter the 04/125 115 228 220 Estation Described Progress 20 to 65

- 5. Inspira is included in the definition of "Other Contributing Parties" in the Plan and accordingly will, if the Plan is confirmed, be the beneficiary of certain releases and injunctions in aid thereof contained in the Plan.
- 6. It is my understanding that courts in this Circuit, when evaluating third-party releases and injunctions (such as the Plan releases and injunctions in favor of Inspira and others), consider the factors set forth in <u>In re Master Mortgage Invest. Fund, Inc.</u>, 168 B.R. 930 (Bankr. W.D. Mo. 1994), including an identity of interest between the debtor and the third party, whether the non-debtor has contributed substantial assets to the estate, and whether the Plan releases and injunction provided in the Plan are essential the success and viability thereof.
- 7. Inspira is a defendant in over a dozen lawsuits in the consolidated MDL Proceeding, alleging personal injury, product liability and negligence claims due to the administration of NECC products. Dozens of proofs of claim have been submitted in this Bankruptcy case by persons who were administered NECC MPA at Inspira and have not yet filed a lawsuit against Inspira. As a result, to the extent Inspira is or becomes liable to any patient who received an injection of NECC MPA, Inspira has claims against NECC for, among others, contribution and indemnification. To this end, on January 14, 2014, Inspira filed a proof of claim [Claim No. 2516] against the NECC estate on those grounds. Absent confirmation of the Plan and the effectiveness of the releases and injunctions contained therein in favor of Inspira, Inspira intends to vigorously pursue its claims against the NECC estate.
- 8. In an effort to resolve Inspira's claims against the NECC estate and the alleged claims of tort claimants against Inspira, Inspira and its insurers participated in two days of mediation and extensive additional negotiations with the Trustee, his counsel, and representatives of both the Official Committee and the Plaintiffs' Steering Committee. The

mediation and additional negotiations were supervised by Eric D. Green of Resolutions LLC. After more than a year of good faith, arm's-length negotiation, Inspira and its insurers Juno Assurance Ltd. ("Juno"), Lexington Insurance Company ("Lexington"), and Ironshore Specialty Insurance Company ("Ironshore") agreed to contribute \$16 million to the NECC estate.

- 9. The Inspira settlement represents the full amount and coverage limit of liability of the remaining aggregate, \$3 million self-insured retention policy with Juno, the full amount and coverage limit of liability of \$10 million of Inspira's second-tier excess insurance policy with Lexington, and a contribution in excess of \$3 million by Inspira's third-tier excess carrier Ironshore.
- 10. Inspira agreed to participate in mediation in part to avoid the expense and delay of protracted litigation relating to Inspira's alleged liability for the harm caused by NECC's products. That being said, Inspira has strong legal and factual defenses to liability in connection with its alleged role in the outbreak, namely that there is absolutely no evidence that Inspira caused or contributed to the contamination of NECC MPA or knew or could have known that NECC produced contaminated MPA.
- 11. Given Inspira's strong defenses, it is far from certain that NECC's tort creditors would be able to realize through litigation the significant sum that Inspira has contributed to the NECC estate and certainly would not be able to realize any recovery whatsoever from Inspira without incurring the delay, expense and risks of litigation (including the risk that one significant judgment in favor of a tort claimant would significantly deplete the amounts available to pay any others).
 - 12. Under all of these circumstances, Inspira's contribution is substantial.

13. The Plan releases and injunctions apply to Inspira, Juno, Lexington and Ironshore, and the persons and entities related to them as described in the settlement agreement [Docket No. 1141]. The Plan provides for Inspira and its insurers to receive a global release and an injunction protecting them from any and all claims by any Person related in any way to NECC or the drugs

NECC compounded.

Inspira would not have settled with the Trustee on terms that did not provide for Inspira and its identified employees, affiliates, and agents to be protected from any and all claims arising from or related to the drugs that NECC compounded, including without limitation (i) claims brought or asserted at present or in the future by the tort claimants, who are to be the principal beneficiaries of Inspira's contributions through the Plan, and (ii) any and all claims for contribution or indemnity. In that same vein, Juno, Lexington and Ironshore would not have agreed to any settlement if there was any risk that any person or entity who was an insured under the applicable insurance policies would seek coverage for any claim related to NECC. Inspira, Juno, Lexington and Ironshore would not have contributed the sums each agreed to contribute without the third party releases and injunction. As such, the third party releases are critical to the settlement.

14. Throughout the mediation process, the mutual understanding among Inspira, Juno, Lexington, Ironshore, the mediator, the Trustee, his counsel, and representatives of both the Official Committee and the Plaintiffs' Steering Committee was that Inspira, Juno, Lexington and Ironshore were only willing to negotiate and enter into a settlement on the condition that any settlement was a final settlement of *all* NECC-related liability - not only that of Inspira, Juno, Lexington and Ironshore, but any potential liability of each of their respective related parties that

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are identified in the settlement agreement. It was with this understanding that Inspira and its

insurers agreed to make its significant contribution to the NECC estate.

15. I understand that Inspira's significant contribution will be an important addition to

a fund to be distributed to NECC's creditors, the majority of whom are victims of NECC's

contaminated product.

16. For all of the reasons set forth above, I believe that the Plan releases and

injunction in favor of Inspira, its insurers, and agents and affiliates of each are not only

appropriate but are in the best interests of NECC's creditors and are essential to consummation

of the proposed Plan.

17. I, on behalf of Inspira, fully support confirmation of the Plan.

I certify and declare under penalty of perjury under the laws of the United States of

America that the foregoing is true and correct to the best of my knowledge and belief.

Executed on the 27th day of April 2015.

Matthew K. Doonan, Esq.

General Counsel

Inspira Health Network, Inc.

PLAN PROPONENTS' EXHIBIT 9

UNITED STATES BANKRUPTCY COURT DISTRICT OF MASSACHUSETTS EASTERN DIVISION

In re:	
NEW ENGLAND COMPOUNDING PHARMACY, INC.,	Chapter 11 Case No. 12-19882-HJB
Debtor.	

DECLARATION OF HENRI G. MINETTE IN SUPPORT OF CONFIRMATION OF FIRST AMENDED JOINT CHAPTER 11 PLAN OF NEW ENGLAND COMPOUNDING PHARMACY, INC.

- I, Henri G. Minette, Esquire, submit this declaration in support of confirmation of the Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. [Docket No. 1054] (as amended at Docket No. 1154 and thereafter from time to time, and including all exhibits and supplements thereto, the "Plan"), and respectfully state as follows:
- 1. I am General Counsel and Secretary of Insight Health Corp. ("Insight"), and I am authorized to make this declaration on Insight's behalf.
- 2. Insight is a company that operates imaging centers nationwide, including a facility located in Roanoke, Virginia. Patients at Insight's Roanoke clinic receive, among other services, image-guided pain therapy. Insight performs the clinic administration and operational support functions at the Roanoke facility.
- 3. New England Compounding Pharmacy, Inc. ("NECC") compounded and sold many different drugs, including preservative-free methylprednisolone acetate ("MPA"). The initial decision to purchase MPA for use at the Roanoke clinic was made during previous ownership of the facility Center for Advanced Imaging, which had purchased and used preservative-free MPA from NECC beginning in 2007. In 2008 the practice was sold to

Carilion, which in turn sold it to Insight in 2010. In summary, MPA was used at the clinic for more than five years by various owners without incident.

- 4. At no time during Insight's ownership of the Roanoke clinic and before the outbreak of fungal meningitis in 2012, did Insight know or have any reason to suspect that NECC was not producing quality drugs in a safe and reliable manner and in accordance with all applicable state and federal laws and regulations.
- 5. Insight does not believe that it engaged in any act or omission that contributed to the injuries and deaths of any of its patients who were treated with MPA made by NECC. Nonetheless, Insight made a decision to settle all pending litigation on the terms set forth in the Plan because of a concern that its liability insurance coverage was insufficient to protect the company if it might be found liable in the face of 47 lawsuits filed by a total of 153 former patients. In addition, cross-claims for contribution and indemnity were asserted against Insight, which had contracted to provide management services to the practice, by co-defendants Image Guided Pain Management, Inc. and Drs. John Mathis and Robert O'Brien, who had contracted to provide professional services to patients at the Roanoke clinic.
- 6. Insight is included in the definition of "Other Contributing Parties" in the Plan and accordingly will, if the Plan is confirmed, be the beneficiary of certain releases and injunctions in aid thereof contained in the Plan.
- 7. I understand that courts in this Circuit, when evaluating third-party releases and injunctions (such as the Plan releases and injunctions in favor of Insight and others), consider the factors set forth in <u>In re Master Mortgage Invest. Fund, Inc.</u>, 168 B.R. 930 (Bankr. W.D. Mo. 1994). The <u>Master Mortgage</u> factors relevant to my declaration include: (i) whether there is an identity of interest between the debtor and the third party, usually an indemnity relationship, such

that a suit against the non-debtor is, in essence, a suit against the debtor or will deplete assets of the estate; (ii) whether the non-debtor has contributed substantial assets to the estate; and (iii) whether the Plan releases and injunction provided in the Plan are essential to the success and viability thereof and whether, without them, there is little likelihood of success. I respectfully submit that, with respect to the Plan releases and injunctions in favor of Insight, its affiliates, and its insurers, those factors are satisfied.

A. There Is an Identity of Interest Between NECC and Insight.

- 8. Insight is presently a defendant in 47 lawsuits involving 153 plaintiffs, originally filed in state court in Virginia and later consolidated in the MDL Proceeding, alleging personal injury or wrongful death due to the administration of NECC products. Insight also is subject to cross-claims asserted by co-defendants for contribution and indemnity in all of the cases. Further, Insight is aware of the risk of other potential claims by other former patients or their families who are not plaintiffs in the suits filed against Insight and pending in the MDL Proceeding.
- 9. To the extent Insight is or becomes liable to any patient who received an injection of NECC MPA, Insight has strong and significant claims against NECC for, *inter alia*, contribution and indemnity. On December 20, 2013, Insight filed a proof of claim (Claim No. 323) (subsequently amended on December 30, 2013 (Claim No. 561), and on January 15, 2014 (Claim No. 2817)) against the NECC estate on those grounds. Absent confirmation of the Plan and the effectiveness of the releases and injunctions contained therein in favor of Insight and its affiliates, Insight intends to pursue its claims against the NECC estate. There is plainly an identity of interest between NECC and Insight.

B. <u>Insight Has Contributed Substantial Assets to the Estate.</u>

- 10. In an effort to resolve Insight's claims against the NECC estate and the alleged claims of tort claimants against Insight, management of Insight and its counsel participated in multiple days of mediation and extensive additional negotiations with the Trustee and his counsel, representatives of both the Official Committee and the Plaintiffs' Steering Committee, and counsel for the 153 plaintiffs represented by nine law firms. The mediation and additional negotiations were supervised by Professor Eric D. Green of Resolutions, LLC, and the Honorable Stanley P. Klein of The McCammon Group. After six months of good faith, arm's-length negotiation, Insight and its insurers, Lexington Insurance Company ("Lexington") and Darwin Select Insurance Company ("Darwin"), agreed to contribute \$38.5 million to the NECC estate. The total settlement amount includes the policy limits of Insight's insurance coverage based upon the coverage positions of Lexington and Darwin, plus a direct contribution by Insight of seven million dollars.
- 11. Insight agreed to participate in mediation in part to avoid the expense and delay of protracted litigation relating to Insight's alleged liability for the harm caused by NECC's products, and insufficient insurance coverage as explained above. That being said, Insight has strong legal and factual defenses to liability in connection with its alleged role in the outbreak.
 - a. Insight did not alter the MPA received from NECC. The vials of MPA were kept unopened, in the original sealed vials as received from NECC, until immediately prior to being used by the physicians in a procedure. To the extent that any patient in Insight's Roanoke facility received contaminated MPA, such contamination occurred at NECC's facilities, without any knowledge of any potential contaminant by Insight and its staff or the physicians who administered the injections.

¹ Insight has reserved its position on an insurance coverage dispute with Lexington.

- b. Insight had no legal duty to protect any NECC victim from the negligent (and potentially criminal) and unforeseeable actions of NECC.
- c. Insight has asserted solid defenses to all of the various legal claims and causes of action asserted by the plaintiffs, and believes that if any case were to be tried, that a jury would conclude Insight did not engage in any act or omission that contributed to the injuries and deaths of any of its patients who were treated with MPA made by NECC.
- 12. It is by no means certain that NECC's tort creditors would be able to realize through litigation the significant sum contributed by and on behalf of Insight to the NECC estate, and certainly would not be able to realize any recovery whatsoever from Insight without incurring the delay, expense and risks of litigation (including the risk that one significant judgment in favor of a tort claimant would significantly deplete the amounts available to pay any others). Under these circumstances and by any measure, the total settlement contribution to the NECC estate by and on behalf of Insight is "substantial." In fact, the contribution by and on behalf of Insight totals about twenty percent (20%) of the entire NECC estate.

C. The Plan Releases and Injunction are Essential to the Success of the Plan.

13. The Plan releases and injunction apply to Insight, Lexington and Darwin, and the persons and entities related to them as described in the settlement agreement. Insight, Lexington and Darwin are to receive global releases and an injunction protecting them from any and all claims by anyone that was related in any way to NECC or the drugs it compounded. The global releases and injunction required under the Insight settlement agreement are to be achieved through confirmation of a plan of reorganization in NECC's bankruptcy case.

- Insight, Lexington and Darwin would not have settled with the Trustee if Insight 14. and its direct and indirect affiliates and their officers, directors, agents and employees were not protected from further third party claims brought by the tort claimants who are to be the principal beneficiaries of their substantial contributions through the Plan, and protected from all contribution, indemnity and other claims. A settlement that did not include corporate affiliates, officers, directors, agents and employees would leave Insight-related entities and individuals at risk for future suits, because there is a subset of possible claims as to which the statute of limitations has not run. This would make Insight vulnerable to future claims for indemnity, because the joint tortfeasor settlement statute in Virginia only extinguishes claims for contribution, and not for indemnity. The need to protect affiliates through the plan releases and injection is not a theoretical "belts and suspenders" protection as two of Insight's corporate affiliates, Insight Health Services Corp. and Insight Health Services Holdings Corp., were sued along with Insight by three of the settling Virginia Plaintiffs (Baker, Johnston and Wertz). Thus, a settlement without protection for affiliates through the plan releases and injunction would mean that at the same time Insight would have exhausted its uncontested insurance coverage of \$31.5 million with Lexington and Darwin (which also covers Insight's affiliates), and paid out an additional seven million dollars (\$7,000,000) of Insight corporate funds, it and its affiliates would continue to have exposure for future claims. There is no way that Insight would settle under such circumstances.
- 15. Lexington's and Darwin's participation in the settlement was motivated by their interest in ending their very substantial obligations to pay Insight's ongoing defense costs. The only way to eliminate this obligation was through the inclusion of the plan releases and an injunction as a condition to settlement. Thus, the third party releases and injunction were critical

to achieving the conditional settlement, which it is important to note is subject to being terminated if the chapter 11 plan is not confirmed with the plan releases and injunction. By the conclusion of the negotiations, Insight, Lexington, Darwin, the mediator, the Trustee and his counsel, representatives of both the Official Committee and the Plaintiffs' Steering Committee, and the 153 plaintiffs, all understood that Insight, Lexington and Darwin were only willing to negotiate and enter into a settlement on the condition that any settlement was a final settlement of *all* NECC-related liability - not only that of Insight, Lexington and Darwin, but any potential liability of related parties, including Insight's direct and indirect affiliates and their present and former officers, directors, agents and employees. It was with this understanding that Insight, Lexington and Darwin agreed to make their significant contribution to the NECC estate.

- 16. I understand that significant contributions by and on behalf of Insight will be an important addition to a fund to be distributed to NECC's creditors, and that absent Insight's contribution, and those of other parties, NECC's estate would have limited, if any, assets available for distributions. Moreover, as described above, in light of Insight's strong defenses to liability, it is by no means certain that NECC's tort creditors would be able to recover any amounts whatsoever from Insight if the Plan were not confirmed and the releases and injunction contained therein were not made effective. And under that scenario, each judgment awarded to an NECC tort creditor would reduce the amount available to pay to other tort creditors, as each claim paid under Insight's insurance policy would reduce the amount available to satisfy other claims.
- 17. For these reasons, I believe that the Plan releases and injunction in favor of Insight, its insurers, and agents and affiliates of each are not only appropriate but are in the best interests of NECC's creditors and are essential to consummation of the proposed Plan.

18. In conclusion, I, on behalf of Insight, respectfully submit that (i) under the circumstances, the relevant Master Mortgage factors are satisfied, (ii) that the Plan releases and injunction are in the best interest of the NECC estate and its creditors, and (iii) that the settlement, as embodied in the Plan, best provides for the equitable distribution of the substantial contribution by and on behalf of Insight to NECC's creditors. I, on behalf of Insight, fully support confirmation of the Plan.

I certify and declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct to the best of my knowledge and belief.

Executed on the 23 day of April 2015.

Henri G. Minette, Esquire

General Counsel Insight Health Corp.

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PLAN PROPONENTS' EXHIBIT 10

UNITED STATES BANKRUPTCY COURT DISTRICT OF MASSACHUSETTS EASTERN DIVISION

In re:	A11.
NEW ENGLAND COMPOUNDING PHARMACY, INC.,	Chapter 11 Case No. 12-19882-HJB
Debtor.	

DECLARATION OF GREGORY EARL THOMAS IN SUPPORT OF CONFIRMATION OF FIRST AMENDED JOINT CHAPTER 11 PLAN OF NEW ENGLAND COMPOUNDING PHARMACY, INC.

- I, Gregory Earl Thomas, submit this declaration in support of confirmation of the Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. [Docket No. 1054] (as amended at Docket No. 1154 and thereafter from time to time, and including all exhibits and supplements thereto, the "Plan"), and respectfully state as follows:
- 1. I am the Vice President Business Development of ARL Biopharma, Inc. d/b/a Analytical Research Laboratories ("ARL"), and I am authorized to make this declaration on ARL's behalf.
- 2. ARL is a small, locally owned, Oklahoma corporation with its place of business in Oklahoma City, Oklahoma.
- 3. New England Compounding Pharmacy, Inc. ("NECC"), the debtor in the above captioned case, compounded and sold many different drugs. ARL provided limited testing services with respect to particular samples of some of the drugs NECC compounded and sold.
- 4. In the pending litigation against ARL, Plaintiffs allege that ARL (i) improperly tested NECC-compounded MPA bearing Lot Numbers 05212012@68, 06292012@26, and 08102012@51, which are the lot numbers associated with the NECC fungal meningitis outbreak; G.Thomas Declaration/ARL/4.14.15, 11:42 p.m./Haupt

(ii) improperly tested NECC-compounded cardioplegia solution from unidentified "lots" or "batches," which are alleged to have caused death; (iii) declared those MPA and cardioplegia solution "lots" or "batches" to be "sterile" and within acceptable endotoxin levels when they were not; and (iv) thereby caused injury.

5. No evidence has been presented that ARL: (i) tested *any* final product from NECC Lot Numbers 05212012@68, 06292012@26, or 08102012@51, for sterility or endotoxins; (ii) tested *any* final product from any lot or batch of NECC-compounded cardioplegia solution allegedly causing injury; (iii) reported any NECC drug samples tested to be "sterile" or within acceptable endotoxin levels when they were not; or (iv) reported that "lots" or "batches" of any NECC-compounded product were "sterile" or within acceptable endotoxin levels. ARL only reported on the samples it tested.

6. Many of the claims made against ARL arise from injections given at facilities to which only 1 or 2 mL vials of NECC-compounded MPA were shipped. The evidence indicates that over 83% of the NECC MPA vials shipped bearing Lot Numbers 05212012@68, 06292012@26, and 08102012@51 were in 1 mL and 2 mL vials. ARL did not test any 1 or 2 mL vials of NECC-compounded MPA marked with the lot numbers implicated in the fungal meningitis outbreak, prior to September 26, 2012, the date of NECC's MPA recall, let alone report they were "sterile" or within acceptable endotoxin levels. Despite facing allegations concerning endotoxin testing deficiencies, ARL is unaware of *any* injury allegedly caused by endotoxins. ARL is adamant that it is not liable to anyone for claims related to any NECC drugs.

- 7. ARL is included in the definition of "Other Contributing Parties" in the Plan and accordingly will, if the Plan is confirmed, be the beneficiary of certain releases and injunctions in aid thereof contained in the Plan.
- 8. I have been advised that courts in this and other Circuits, when evaluating thirdparty releases and injunctions (such as the Plan releases and injunctions in favor of ARL and
 others), consider such factors as(i) whether there is an identity of interest between the debtor and
 the third party, usually an indemnity relationship, such that a suit against the non-debtor is, in
 essence, a suit against the debtor or will deplete assets of the estate; (ii) whether the non-debtor
 has contributed substantial assets to the estate; and (iii) whether the Plan releases and injunction
 provided in the Plan are essential to the success and viability thereof and whether, without them,
 there is little likelihood of success. I respectfully submit that, with respect to the Plan releases
 and injunctions in favor of ARL, its affiliates, and its insurers, those factors are satisfied.

A. There Is an Identity of Interest Between NECC and ARL.

9. ARL has been made the subject of more than 200 lawsuits in both state and federal courts, including those consolidated in the MDL Proceeding, alleging personal injury or wrongful death due to the administration of NECC products. Further, ARL has received notices of intent to sue and other threats of litigation from hundreds of other potential plaintiffs. Accordingly, to the extent ARL is or becomes liable to any patient who received an injection of NECC MPA, ARL has strong and significant claims against NECC for, *inter alia*, contribution and indemnity. On January 10, 2014, ARL filed a proof of claim [Claim No. 63] against the NECC estate on those grounds. Absent confirmation of the Plan and the effectiveness of the releases and injunctions contained therein in favor of ARL and its affiliates, ARL intends to

pursue its claims against the NECC estate. There is plainly an identity of interest between NECC and ARL.

B. ARL Has Contributed Substantial Assets to the Estate.

- ln an effort to resolve ARL's claims against the NECC estate and the alleged claims of tort claimants against ARL, I, along with other management of ARL and its counsel participated in two days of mediation and extensive additional negotiation with the Trustee, his counsel, and representatives of both the Official Committee and the Plaintiffs' Steering Committee. The mediation and additional negotiations were supervised by Carmen Reiss of Resolutions LLC. After more than eight months of good faith, arm's-length negotiation, ARL and its insurer(s) Landmark American Insurance Company ("Landmark") agreed to contribute \$6.4 million to the NECC estate. This settlement amount represents the policy limits of ARL's Landmark coverage, plus other funds paid directly by ARL.
- 11. ARL agreed to participate in mediation in part to avoid the expense and delay of protracted litigation relating to ARL's alleged liability for the harm caused by NECC's products. That being said, ARL has strong legal and factual defenses to liability in connection with its alleged role in the outbreak.
 - a. The evidence to date indicates ARL did not test NECC final product. There is no evidence ARL tested any NECC samples that were actually contaminated and that it reported a false-negative result, i.e., reported a sample to be "sterile" when it was not, or reported a sample to be within acceptable endotoxin limits when it was not.
 - b. Further, no one can show i) that ARL tested final product from any of the lots of MPA implicated in the NECC fungal meningitis outbreak or cardioplegia solution;

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ii) that *any* test ARL conducted yielded an inaccurate result; or iii) that any act or omission by ARL caused damage to NECC or to any NECC victim.

c. Finally, although ARL contended that the Landmark policy provides \$6.0 million in aggregate coverage, Landmark denied that the aggregate limit applies and sought a judicial declaration to that effect. Without Landmark's agreement to participate in the settlement, it is unclear what amount would be available to pay NECC victims from ARL's insurance coverage. Moreover, since this is a declining policy with its coverage amount being reduced by the costs of defense, without the settlement, it is likely that there would be no coverage, or at least greatly reduced coverage, available to pay NECC victims.

12. It is by no means certain that NECC's tort creditors would be able to realize through litigation the significant sum that ARL has contributed to the NECC estate, and certainly would not be able to realize any recovery whatsoever from ARL without incurring the delay, expense and risks of litigation (including the risk that one significant judgment in favor of a tort claimant would significantly deplete the amounts available to pay any others). Under these circumstances, ARL's contribution is "substantial."

C. The Plan Releases and Injunction are Essential to the Success of the Plan.

11. The Plan releases and injunctions apply to ARL and Landmark, and the persons and entities related to them as described in the settlement agreement. ARL and Landmark are to receive global releases and an injunction protecting them from any and all claims by anyone that were related in any way to NECC or the drugs it compounded. The global releases and injunction required under the ARL settlement agreement were to be achieved through confirmation of a plan of reorganization in NECC's bankruptcy case.

- 12. ARL would not have settled with the Trustee or have waived its rights to defense under the applicable insurance policies if ARL and its employees, affiliates, and agents were not protected from further third party claims brought by the tort claimants who are to be the principal beneficiaries of ARL's contributions through the Plan, and protected from all contribution, indemnity and other claims related to NECC and drugs compounded by it. In that same vein, Landmark would not have agreed to any settlement if there was any risk that any person or entity who was an insured under the applicable insurance policy would seek reimbursement of defense costs to defend any claims against any of them. The only way to eliminate the risk of further defense costs to these insureds was to provide third party releases and an injunction to eliminate the need for them to defend themselves from any claims, and in exchange to secure from the insureds the "policy releases" Landmark required as a condition to settlement. Effectively, all of the beneficiaries of the third party releases and injunction are contributors in that Landmark could not have contributed what it intends to contribute without the third party releases of all putative insureds, including those not directly contributing funds towards the settlement. Thus, the third party releases and injunction were critical to the settlement.
- 13. Throughout the settlement negotiations, the mutual understanding among ARL, Landmark, the mediator, the Trustee, and representatives of both the Official Committee and the Plaintiffs' Steering Committee was that what ARL and Landmark were only willing to negotiate and enter into a settlement on the condition that any settlement was a final settlement of *all* NECC-related liability not only that of ARL and Landmark, but any potential liability of its related parties, including ARL's officers, directors, employees and other agents and its affiliates. It was with this understanding that ARL agreed to make its significant contribution to the NECC estate.

- 14. I understand that ARL's significant contribution will be an important addition to a fund to be distributed to NECC's creditors, and that absent ARL's contribution, and those of other parties, NECC's estate would have limited, if any, assets available for distributions. Moreover, as described above, in light of ARL's strong defenses to liability, it is by no means certain that NECC's tort creditors would be able to recover any amounts from, or even to obtain any judgments against ARL if the Plan were not confirmed and the releases and injunction contained therein were not made effective. And even if judgments could be and were obtained, each judgment awarded to an NECC tort creditor would reduce the amount available to pay to other tort creditors, as each claim paid under ARL's insurance policy would reduce the amount available to satisfy other claims, as would the costs of continuing to defend the hundreds of pending cases.
- 15. For these reasons, I believe that the Plan releases and injunction in favor of ARL, its insurer, and agents and affiliates of each are not only appropriate but are in the best interests of NECC's creditors and are essential to consummation of the proposed Plan.
- 16. In sum, I, on behalf of ARL, respectfully submit that (i) under the circumstances, the relevant required factors are satisfied, (ii) that the Plan releases and injunction are in the best interest of the NECC estate and its creditors, and (iii) that the settlement, as embodied in the Plan, best provides for the equitable distribution of ARL's substantial contribution to NECC's creditors. I, on behalf of ARL, fully support confirmation of the Plan.

I certify and declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct to the best of my knowledge and belief.

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Executed on the 27 day of April 2015.

Gregory Earl Thomas

Vice President Business Development

ARL BioPharma, Inc. d/b/a Analytical Research

Laboratories